Dossier zur Nutzenbewertung gemäß § 35a SGB V

Upadacitinib (RINVOQ®)

AbbVie Deutschland GmbH & Co. KG

Separater Anhang 4-G: Ergänzende Unterlagen

Behandlung der mittelschweren bis schweren atopischen Dermatitis bei Erwachsenen und Jugendlichen ab 12 Jahren, die für eine kontinuierliche systemische Therapie infrage kommen

Stand: 31.08.2021

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Ergänzende Unterlagen zur Studie Heads-Up (M16-046)

Ergänzende Unterlagen zu den Studien
Measure-Up 1 (M16-045) & Measure-Up 2 (M18-891)

- Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
- Adults (>= 18 years of age at the time of the screening visit)

Ergänzende Unterlagen zur Studie AD-Up (M16-047)

- Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
- Adults (>= 18 years of age at the time of the screening visit)

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Table 1.1
Demographic and Baseline Characteristics
(ITT Population)

		Upadacitinib (N=348)	Dupilumab (N=344)	Total (N=692)
Age (years)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	36.58 (14.61)	36.89 (14.09)	36.74 (14.34)
	Median	32.00	33.00	33.00
	Q1, Q3	24.50, 46.50	26.00, 48.00	25.00, 47.00
	Min, Max	18.00, 76.00	18.00, 76.00	18.00, 76.00
Age Group (years) - n (%)	< 40	228 (65.5)	226 (65.7)	454 (65.6)
	40 - < 65	102 (29.3)	101 (29.4)	203 (29.3)
	>=65	18 (5.2)	17 (4.9)	35 (5.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Age Subgroup (years) - n (%)	< 40	228 (65.5)	226 (65.7)	454 (65.6)
	>=40	120 (34.5)	118 (34.3)	238 (34.4)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Sex - n (%)	Female	165 (47.4)	150 (43.6)	315 (45.5)
	Male	183 (52.6)	194 (56.4)	377 (54.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Race - n (%)	White	235 (67.5)	244 (70.9)	479 (69.2)
	Black	25 (7.2)	15 (4.4)	40 (5.8)
	Asian	77 (22.1)	78 (22.7)	155 (22.4)
	Other	11 (3.2)	7 (2.0)	18 (2.6)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Race Subgroup - n (%)	White	235 (67.5)	244 (70.9)	479 (69.2)
	Asian	77 (22.1)	78 (22.7)	155 (22.4)
	Other	36 (10.3)	22 (6.4)	58 (8.4)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Geographic Region - n (%)	US/PR/Canada	140 (40.2)	131 (38.1)	271 (39.2)
	Other	208 (59.8)	213 (61.9)	421 (60.8)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Weight (kg)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	78.77 (22.28)	75.55 (18.39)	77.17 (20.49)
	Median	74.60	73.05	73.85
	Q1, Q3	62.45, 90.00	63.00, 85.80	62.75, 87.40
	Min, Max	39.00, 168.30	40.10, 160.00	39.00, 168.30
Weight (kg) - n (%)	< Median (73.90)	167 (48.0)	179 (52.0)	346 (50.0)
	>= Median (73.90)	181 (52.0)	165 (48.0)	346 (50.0)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Body Mass Index (kg/m^2)	n (missing)	347 (1)	344 (0)	691 (1)
	Mean (SD)	26.99 (6.53)	25.99 (5.72)	26.49 (6.16)
	Median	25.60	25.05	25.20
	Q1, Q3	22.10, 30.80	21.80, 28.60	22.00, 29.40
	Min, Max	15.20, 60.70	15.70, 54.10	15.20, 60.70
Body Mass Index (kg/m^2) - n (%)	< 25	161 (46.4)	169 (49.1)	330 (47.8)
	25 - < 30	93 (26.8)	110 (32.0)	203 (29.4)
	>= 30	93 (26.8)	65 (18.9)	158 (22.9)
	Missing	1 (0.3)	0 (0.0)	1 (0.1)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, HN-PGIS: Head and Neck - Patient Global Impression of Severity
Disease duration since diagnosis is calculated as (date of first dose of study drug – date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25

Table 1.1
Demographic and Baseline Characteristics
(ITT Population)

		Upadacitinib (N=348)	Dupilumab (N=344)	Total (N=692)
Baseline EASI	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	30.75 (12.54)	28.81 (11.51)	29.79 (12.07)
	Median	27.30	25.50	26.40
	Q1, Q3	20.60, 37.95	19.75, 34.45	20.15, 36.45
	Min, Max	16.00, 70.80	16.00, 69.60	16.00, 70.80
Baseline EASI - n (%)	< Median (26.4)	165 (47.4)	180 (52.3)	345 (49.9)
	>= Median (26.4)	183 (52.6)	164 (47.7)	347 (50.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline vIGA-AD	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	3.50 (0.50)	3.50 (0.50)	3.50 (0.50)
	Median	3.50	4.00	4.00
	Q1, Q3	3.00, 4.00	3.00, 4.00	3.00, 4.00
	Min, Max	3.00, 4.00	3.00, 4.00	3.00, 4.00
Baseline vIGA-AD - n (%)	3 (Moderate)	174 (50.0)	171 (49.7)	345 (49.9)
	4 (Severe)	174 (50.0)	173 (50.3)	347 (50.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline hsCRP	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	4.83 (8.26)	3.43 (5.56)	4.13 (7.08)
	Median	1.99	1.64	1.75
	Q1, Q3	0.77, 5.44	0.58, 3.86	0.67, 4.57
	Min, Max	0.20, 60.60	0.20, 45.90	0.20, 60.60
Baseline hsCRP - n (%)	< Median (1.745)	161 (46.3)	185 (53.8)	346 (50.0)
	>= Median (1.745)	187 (53.7)	159 (46.2)	346 (50.0)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Topical Therapy - n (%)	With	334 (96.0)	327 (95.1)	661 (95.5)
	Without	14 (4.0)	17 (4.9)	31 (4.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Systemic Therapy - n (%)	With	180 (51.7)	175 (50.9)	355 (51.3)
	Without	168 (48.3)	169 (49.1)	337 (48.7)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Phototherapy - n (%)	With	60 (17.2)	57 (16.6)	117 (16.9)
	Without	288 (82.8)	287 (83.4)	575 (83.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline BSA	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	48.20 (23.96)	44.41 (22.83)	46.32 (23.47)
	Median	42.00	40.00	40.00
	Q1, Q3	29.00, 70.00	25.50, 60.00	27.00, 65.00
	Min, Max	10.00, 100.00	10.00, 98.00	10.00, 100.00
Worst Pruritus NRS (Weekly Average)	n (missing)	346 (2)	342 (2)	688 (4)
	Mean (SD)	7.44 (1.56)	7.51 (1.68)	7.47 (1.62)
	Median	7.50	7.71	7.60
	Q1, Q3	6.57, 8.50	6.43, 8.71	6.54, 8.57
	Min, Max	1.14, 10.00	0.57, 10.00	0.57, 10.00
Worst Pruritus NRS (Weekly Average) - n (%)	<= 6	64 (18.5)	66 (19.3)	130 (18.9)
	> 6	282 (81.5)	276 (80.7)	558 (81.1)
	Missing	2 (0.6)	2 (0.6)	4 (0.6)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, HN-PGIS: Head and Neck - Patient Global Impression of Severity
Disease duration since diagnosis is calculated as (date of first dose of study drug – date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25

Table 1.1
Demographic and Baseline Characteristics
(ITT Population)

		Upadacitinib (N=348)	Dupilumab (N=344)	Total (N=692)
Baseline HN-PGIS	n (missing)	348 (0)	341 (3)	689 (3)
	Mean (SD)	3.79 (1.60)	3.95 (1.46)	3.87 (1.53)
	Median	4.00	4.00	4.00
	Q1, Q3	3.00, 5.00	3.00, 5.00	3.00, 5.00
	Min, Max	0.00, 6.00	0.00, 6.00	0.00, 6.00
Disease duration since diagnosis (years)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	23.46 (14.72)	25.05 (14.79)	24.25 (14.77)
	Median	23.05	23.52	23.19
	Q1, Q3	12.11, 31.35	15.45, 32.33	14.12, 32.06
	Min, Max	0.11, 70.18	0.03, 75.44	0.03, 75.44
Any Allergic Comorbidity - n (%)	With	249 (71.6)	263 (76.5)	512 (74.0)
	Without	99 (28.4)	81 (23.5)	180 (26.0)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Food Allergy - n (%)	With	110 (31.6)	122 (35.5)	232 (33.5)
	Without	238 (68.4)	222 (64.5)	460 (66.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Asthma - n (%)	With	146 (42.0)	144 (41.9)	290 (41.9)
	Without	202 (58.0)	200 (58.1)	402 (58.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Allergic Rhinitis - n (%)	With	176 (50.6)	187 (54.4)	363 (52.5)
	Without	172 (49.4)	157 (45.6)	329 (47.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Eosinophilic Esophagitis - n (%)	With	0 (0.0)	1 (0.3)	1 (0.1)
	Without	348 (100.0)	343 (99.7)	691 (99.9)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Nasal Polyps - n (%)	With	7 (2.0)	6 (1.7)	13 (1.9)
	Without	341 (98.0)	338 (98.3)	679 (98.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, HN-PGIS: Head and Neck - Patient Global Impression of Severity
Disease duration since diagnosis is calculated as (date of first dose of study drug – date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25

Table 1.2
Subject Disposition
(ITT Population)

Status	Upadacitinib(N=348) n (%)	Dupilumab(N=344) n (%)	Total(N=692) n (%)
Received study drug	348 (100.0)	344 (100.0)	692 (100.0)
Received rescue medication	88 (25.3)	85 (24.7)	173 (25.0)
Received topical rescue medication	83 (23.9)	82 (23.8)	165 (23.8)
Plain topical corticosteroid	79 (22.7)	75 (21.8)	154 (22.3)
High potency topical corticosteroid	56 (16.1)	47 (13.7)	103 (14.9)
Medium potency topical corticosteroid	31 (8.9)	38 (11.0)	69 (10.0)
Low potency topical corticosteroid	17 (4.9)	16 (4.7)	33 (4.8)
Topical calcineurin inhibitor	14 (4.0)	22 (6.4)	36 (5.2)
Other topical therapy	0 (0.0)	0 (0.0)	0 (0.0)
Received systemic rescue medication	14 (4.0)	4 (1.2)	18 (2.6)
Biologic systemic therapy	7 (2.0)	2 (0.6)	9 (1.3)
Non-biologic immunomodulating systemic therapy	8 (2.3)	2 (0.6)	10 (1.4)
Other systemic therapy	0 (0.0)	0 (0.0)	0 (0.0)
Received rescue phototherapy	0 (0.0)	1 (0.3)	1 (0.1)
Completed study	318 (91.4)	320 (93.0)	638 (92.2)
Ongoing study	0 (0.0)	0 (0.0)	0 (0.0)
Discontinued study	30 (8.6)	24 (7.0)	54 (7.8)
Primary reason			
Adverse event	7 (2.0)	3 (0.9)	10 (1.4)
Withdrawal of consent	11 (3.2)	8 (2.3)	19 (2.7)
Lost to follow-up	5 (1.4)	8 (2.3)	13 (1.9)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	1 (0.3)	1 (0.3)	2 (0.3)
Other	6 (1.7)	4 (1.2)	10 (1.4)
Completed on study drug	316 (90.8)	319 (92.7)	635 (91.8)
Ongoing on study drug	0 (0.0)	0 (0.0)	0 (0.0)
Discontinued study drug	32 (9.2)	25 (7.3)	57 (8.2)
Primary reason			
Adverse event	10 (2.9)	4 (1.2)	14 (2.0)
Withdrawal of consent	8 (2.3)	6 (1.7)	14 (2.0)
Lost to follow-up	4 (1.1)	5 (1.5)	9 (1.3)
Lack of efficacy	6 (1.7)	3 (0.9)	9 (1.3)
EASI score - worsening of 25%	0 (0.0)	0 (0.0)	0 (0.0)
Systemic rescue	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	1 (0.3)	2 (0.6)	3 (0.4)
Other	3 (0.9)	5 (1.5)	8 (1.2)

N: Number of subjects, n: Number of subjects with non-missing status, EASI: Eczema Area and Severity Index, COVID: Corona Virus Disease
One patient may receive more than one rescue therapy (topical, systemic, phototherapy).
If a patient receives systemic rescue therapy the primary reason for discontinuation of study drug does not necessarily have to be systemic rescue.

Table 1.3
Duration of Study and Treatment and Endpoint Observation time
(ITT Population)

		Upadacitinib (N=348)	Dupilumab (N=344)	Total (N=692)
Study duration (Weeks)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	26.23 (5.51)	25.78 (5.99)	26.01 (5.75)
	Median	24.29	24.29	24.29
	Q1, Q3	24.14, 27.64	24.14, 25.36	24.14, 26.29
	Min, Max	1.29, 38.29	1.14, 39.86	1.14, 39.86
Treatment duration (Weeks)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	23.21 (3.52)	22.91 (4.27)	23.06 (3.91)
	Median	24.14	24.00	24.00
	Q1, Q3	23.86, 24.29	23.86, 24.14	23.86, 24.14
	Min, Max	1.14, 26.29	2.00, 26.43	1.14, 26.43
Observation time for safety (Weeks)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	27.49 (3.58)	33.05 (4.27)	30.25 (4.82)
	Median	28.43	34.14	29.07
	Q1, Q3	28.14, 28.57	34.00, 34.29	28.29, 34.14
	Min, Max	5.43, 30.57	12.14, 36.57	5.43, 36.57
Body Surface Area (BSA): Observation time (Weeks)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	23.15 (3.87)	22.96 (4.58)	23.05 (4.23)
	Median	24.14	24.14	24.14
	Q1, Q3	24.00, 24.29	24.00, 24.29	24.00, 24.29
	Min, Max	0.14, 25.43	0.14, 25.43	0.14, 25.43
Eczema Area and Severity Index (EASI): Observation time (Weeks)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	23.15 (3.87)	22.96 (4.58)	23.05 (4.23)
	Median	24.14	24.14	24.14
	Q1, Q3	24.00, 24.29	24.00, 24.29	24.00, 24.29
	Min, Max	0.14, 25.43	0.14, 25.43	0.14, 25.43
Head and Neck - Patient Global Impression of Severity (HN-PGIS): Observation time (Weeks)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	22.83 (4.42)	22.78 (4.82)	22.81 (4.62)
	Median	24.14	24.14	24.14
	Q1, Q3	24.00, 24.29	24.00, 24.29	24.00, 24.29
	Min, Max	0.14, 25.43	0.14, 25.43	0.14, 25.43
Worst Pruritus NRS: Observation time (Weeks)	n (missing)	348 (0)	344 (0)	692 (0)
	Mean (SD)	23.06 (3.56)	22.92 (4.30)	22.99 (3.94)
	Median	24.14	24.14	24.14
	Q1, Q3	23.86, 24.29	24.00, 24.29	23.86, 24.29
	Min, Max	1.14, 25.00	0.14, 25.00	0.14, 25.00

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum, NRS: Numeric Rating Scale
Study duration is calculated as (date of first dose of study drug - minimum(date of end of study, database lock date) + 1) divided by 7
Treatment duration of Upadacitinib is calculated as (date of first dose of study drug - date of last dose of study drug + 1) divided by 7
Treatment duration of Dupilumab is calculated as (date of first dose of study drug - date of last dose of study drug + 14) divided by 7
Observation time for Safety in Upadacitinib arm is calculated as (date of first dose of study drug - minimum(date of last dose of study drug + 30, death date, database lock date) + 1) divided by 7
Observation time for Safety in Dupilumab arm is calculated as (date of first dose of study drug - minimum(date of last dose of study drug + 84, death date, database lock date) + 1) divided by 7
Observation time for endpoints is calculated as (date of first dose of study drug - date of last non-missing evaluation + 1) divided by 7. Evaluations after start of systemic rescue or phototherapy are excluded.

Table 1.4
Overview Completion Rates
(ITT Population)

Endpoint	Visit	Upadacitinib(N=348) n (%)	Dupilumab(N=344) n (%)
Worst Pruritus Numeric Rating Scale	Baseline	346 (99.4)	342 (99.4)
	Week 1	341 (98.0)	340 (98.8)
	Week 2	342 (98.3)	339 (98.5)
	Week 3	344 (98.9)	337 (98.0)
	Week 4	340 (97.7)	332 (96.5)
	Week 5	337 (96.8)	330 (95.9)
	Week 6	336 (96.6)	323 (93.9)
	Week 7	334 (96.0)	325 (94.5)
	Week 8	333 (95.7)	323 (93.9)
	Week 9	329 (94.5)	323 (93.9)
	Week 10	328 (94.3)	324 (94.2)
	Week 11	327 (94.0)	324 (94.2)
	Week 12	328 (94.3)	320 (93.0)
	Week 13	327 (94.0)	320 (93.0)
	Week 14	321 (92.2)	319 (92.7)
	Week 15	318 (91.4)	313 (91.0)
	Week 16	310 (89.1)	305 (88.7)
	Week 18	263 (75.6)	267 (77.6)
	Week 20	311 (89.4)	302 (87.8)
	Week 22	300 (86.2)	291 (84.6)
	Week 24	294 (84.5)	299 (86.9)
Head and Neck - Patient Global Impression of Severity (HN-PGIS)	Baseline	348 (100.0)	341 (99.1)
	Week 1	315 (90.5)	315 (91.6)
	Week 2	335 (96.3)	327 (95.1)
	Week 4	330 (94.8)	325 (94.5)
	Week 8	327 (94.0)	314 (91.3)
	Week 12	320 (92.0)	312 (90.7)
	Week 16	313 (89.9)	313 (91.0)
	Week 20	311 (89.4)	303 (88.1)
	Week 24	308 (88.5)	307 (89.2)

N: Number of subjects, n: Number of subjects with non missing values
All observed data will be used in the analysis.

Table 1.5
Overview Missings and Rescue Therapy
(ITT Population)

		Upadacitinib(N=348)							Dupilumab(N=344)						
		missings			rescue therapy				missings			rescue therapy			
Endpoint	Visit	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)
EASI	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	23 (6.6)	10 (2.9)	13 (3.7)	2 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	25 (7.3)	8 (2.3)	17 (4.9)	3 (0.9)	3 (0.9)	0 (0.0)	0 (0.0)
	Week 2	10 (2.9)	7 (2.0)	3 (0.9)	3 (0.9)	3 (0.9)	0 (0.0)	0 (0.0)	8 (2.3)	5 (1.5)	3 (0.9)	14 (4.1)	14 (4.1)	0 (0.0)	0 (0.0)
	Week 4	9 (2.6)	2 (0.6)	7 (2.0)	5 (1.4)	5 (1.4)	0 (0.0)	0 (0.0)	13 (3.8)	11 (3.2)	2 (0.6)	20 (5.8)	20 (5.8)	0 (0.0)	0 (0.0)
	Week 8	10 (2.9)	5 (1.4)	5 (1.4)	24 (6.9)	24 (6.9)	0 (0.0)	0 (0.0)	19 (5.5)	13 (3.8)	6 (1.7)	37 (10.8)	37 (10.8)	0 (0.0)	0 (0.0)
	Week 12	18 (5.2)	11 (3.2)	7 (2.0)	42 (12.1)	41 (11.8)	1 (0.3)	0 (0.0)	19 (5.5)	14 (4.1)	5 (1.5)	50 (14.5)	50 (14.5)	0 (0.0)	0 (0.0)
	Week 16	26 (7.5)	19 (5.5)	7 (2.0)	48 (13.8)	47 (13.5)	1 (0.3)	0 (0.0)	25 (7.3)	21 (6.1)	4 (1.2)	60 (17.4)	59 (17.2)	1 (0.3)	0 (0.0)
	Week 20	26 (7.5)	23 (6.6)	3 (0.9)	59 (17.0)	58 (16.7)	1 (0.3)	0 (0.0)	32 (9.3)	25 (7.3)	7 (2.0)	66 (19.2)	65 (18.9)	1 (0.3)	0 (0.0)
	Week 24	33 (9.5)	30 (8.6)	3 (0.9)	69 (19.8)	66 (19.0)	3 (0.9)	0 (0.0)	30 (8.7)	28 (8.1)	2 (0.6)	74 (21.5)	73 (21.2)	1 (0.3)	0 (0.0)
Pruritus	Baseline	2 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	7 (2.0)	7 (2.0)	0 (0.0)	2 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	4 (1.2)	3 (0.9)	1 (0.3)	11 (3.2)	11 (3.2)	0 (0.0)	0 (0.0)
	Week 2	6 (1.7)	5 (1.4)	1 (0.3)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	5 (1.5)	4 (1.2)	1 (0.3)	14 (4.1)	14 (4.1)	0 (0.0)	0 (0.0)
	Week 3	4 (1.1)	3 (0.9)	1 (0.3)	4 (1.1)	4 (1.1)	0 (0.0)	0 (0.0)	7 (2.0)	6 (1.7)	1 (0.3)	20 (5.8)	20 (5.8)	0 (0.0)	0 (0.0)
	Week 4	8 (2.3)	7 (2.0)	1 (0.3)	5 (1.4)	5 (1.4)	0 (0.0)	0 (0.0)	12 (3.5)	11 (3.2)	1 (0.3)	20 (5.8)	20 (5.8)	0 (0.0)	0 (0.0)
	Week 5	11 (3.2)	10 (2.9)	1 (0.3)	9 (2.6)	9 (2.6)	0 (0.0)	0 (0.0)	14 (4.1)	13 (3.8)	1 (0.3)	25 (7.3)	25 (7.3)	0 (0.0)	0 (0.0)
	Week 6	12 (3.4)	11 (3.2)	1 (0.3)	13 (3.7)	13 (3.7)	0 (0.0)	0 (0.0)	21 (6.1)	20 (5.8)	1 (0.3)	27 (7.8)	27 (7.8)	0 (0.0)	0 (0.0)
	Week 7	14 (4.0)	13 (3.7)	1 (0.3)	20 (5.7)	20 (5.7)	0 (0.0)	0 (0.0)	19 (5.5)	18 (5.2)	1 (0.3)	33 (9.6)	33 (9.6)	0 (0.0)	0 (0.0)
	Week 8	15 (4.3)	14 (4.0)	1 (0.3)	21 (6.0)	21 (6.0)	0 (0.0)	0 (0.0)	21 (6.1)	20 (5.8)	1 (0.3)	37 (10.8)	37 (10.8)	0 (0.0)	0 (0.0)
	Week 9	19 (5.5)	18 (5.2)	1 (0.3)	31 (8.9)	31 (8.9)	0 (0.0)	0 (0.0)	21 (6.1)	20 (5.8)	1 (0.3)	38 (11.0)	38 (11.0)	0 (0.0)	0 (0.0)
	Week 10	20 (5.7)	18 (5.2)	2 (0.6)	34 (9.8)	34 (9.8)	0 (0.0)	0 (0.0)	20 (5.8)	19 (5.5)	1 (0.3)	41 (11.9)	41 (11.9)	0 (0.0)	0 (0.0)
	Week 11	21 (6.0)	19 (5.5)	2 (0.6)	43 (12.4)	42 (12.1)	1 (0.3)	0 (0.0)	20 (5.8)	19 (5.5)	1 (0.3)	48 (14.0)	48 (14.0)	0 (0.0)	0 (0.0)
	Week 12	20 (5.7)	18 (5.2)	2 (0.6)	42 (12.1)	41 (11.8)	1 (0.3)	0 (0.0)	24 (7.0)	23 (6.7)	1 (0.3)	50 (14.5)	50 (14.5)	0 (0.0)	0 (0.0)
	Week 13	21 (6.0)	19 (5.5)	2 (0.6)	47 (13.5)	46 (13.2)	1 (0.3)	0 (0.0)	24 (7.0)	23 (6.7)	1 (0.3)	54 (15.7)	54 (15.7)	0 (0.0)	0 (0.0)
	Week 14	27 (7.8)	25 (7.2)	2 (0.6)	47 (13.5)	46 (13.2)	1 (0.3)	0 (0.0)	25 (7.3)	24 (7.0)	1 (0.3)	57 (16.6)	56 (16.3)	1 (0.3)	0 (0.0)
	Week 15	30 (8.6)	28 (8.0)	2 (0.6)	49 (14.1)	48 (13.8)	1 (0.3)	0 (0.0)	31 (9.0)	30 (8.7)	1 (0.3)	56 (16.3)	55 (16.0)	1 (0.3)	0 (0.0)
	Week 16	38 (10.9)	36 (10.3)	2 (0.6)	50 (14.4)	49 (14.1)	1 (0.3)	0 (0.0)	39 (11.3)	38 (11.0)	1 (0.3)	53 (15.4)	52 (15.1)	1 (0.3)	0 (0.0)
	Week 18	85 (24.4)	79 (22.7)	6 (1.7)	45 (12.9)	44 (12.6)	1 (0.3)	0 (0.0)	77 (22.4)	72 (20.9)	5 (1.5)	57 (16.6)	56 (16.3)	1 (0.3)	0 (0.0)
	Week 20	37 (10.6)	35 (10.1)	2 (0.6)	56 (16.1)	55 (15.8)	1 (0.3)	0 (0.0)	42 (12.2)	38 (11.0)	4 (1.2)	63 (18.3)	62 (18.0)	1 (0.3)	0 (0.0)
	Week 22	48 (13.8)	44 (12.6)	4 (1.1)	63 (18.1)	62 (17.8)	1 (0.3)	0 (0.0)	53 (15.4)	49 (14.2)	4 (1.2)	67 (19.5)	66 (19.2)	1 (0.3)	0 (0.0)
	Week 24	54 (15.5)	52 (14.9)	2 (0.6)	64 (18.4)	61 (17.5)	3 (0.9)	0 (0.0)	45 (13.1)	44 (12.8)	1 (0.3)	70 (20.3)	69 (20.1)	1 (0.3)	0 (0.0)
BSA	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	23 (6.6)	10 (2.9)	13 (3.7)	2 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	25 (7.3)	8 (2.3)	17 (4.9)	3 (0.9)	3 (0.9)	0 (0.0)	0 (0.0)
	Week 2	10 (2.9)	7 (2.0)	3 (0.9)	3 (0.9)	3 (0.9)	0 (0.0)	0 (0.0)	7 (2.0)	4 (1.2)	3 (0.9)	14 (4.1)	14 (4.1)	0 (0.0)	0 (0.0)
	Week 4	9 (2.6)	2 (0.6)	7 (2.0)	5 (1.4)	5 (1.4)	0 (0.0)	0 (0.0)	13 (3.8)	11 (3.2)	2 (0.6)	20 (5.8)	20 (5.8)	0 (0.0)	0 (0.0)
	Week 8	11 (3.2)	6 (1.7)	5 (1.4)	23 (6.6)	23 (6.6)	0 (0.0)	0 (0.0)	20 (5.8)	14 (4.1)	6 (1.7)	36 (10.5)	36 (10.5)	0 (0.0)	0 (0.0)
	Week 12	17 (4.9)	11 (3.2)	6 (1.7)	42 (12.1)	41 (11.8)	1 (0.3)	0 (0.0)	19 (5.5)	14 (4.1)	5 (1.5)	50 (14.5)	50 (14.5)	0 (0.0)	0 (0.0)
	Week 16	26 (7.5)	19 (5.5)	7 (2.0)	48 (13.8)	47 (13.5)	1 (0.3)	0 (0.0)	26 (7.6)	22 (6.4)	4 (1.2)	60 (17.4)	59 (17.2)	1 (0.3)	0 (0.0)
	Week 20	26 (7.5)	23 (6.6)	3 (0.9)	59 (17.0)	58 (16.7)	1 (0.3)	0 (0.0)	32 (9.3)	25 (7.3)	7 (2.0)	66 (19.2)	65 (18.9)	1 (0.3)	0 (0.0)
	Week 24	33 (9.5)	30 (8.6)	3 (0.9)	69 (19.8)	66 (19.0)	3 (0.9)	0 (0.0)	30 (8.7)	28 (8.1)	2 (0.6)	74 (21.5)	73 (21.2)	1 (0.3)	0 (0.0)
HN-PGIS	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.9)	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	33 (9.5)	21 (6.0)	12 (3.4)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	29 (8.4)	16 (4.7)	13 (3.8)	3 (0.9)	3 (0.9)	0 (0.0)	0 (0.0)
	Week 2	13 (3.7)	10 (2.9)	3 (0.9)	3 (0.9)	3 (0.9)	0 (0.0)	0 (0.0)	17 (4.9)	14 (4.1)	3 (0.9)	14 (4.1)	14 (4.1)	0 (0.0)	0 (0.0)
	Week 4	18 (5.2)	12 (3.4)	6 (1.7)	5 (1.4)	5 (1.4)	0 (0.0)	0 (0.0)	19 (5.5)	15 (4.4)	4 (1.2)	19 (5.5)	19 (5.5)	0 (0.0)	0 (0.0)
	Week 8	21 (6.0)	14 (4.0)	7 (2.0)	24 (6.9)	24 (6.9)	0 (0.0)	0 (0.0)	30 (8.7)	21 (6.1)	9 (2.6)	36 (10.5)	36 (10.5)	0 (0.0)	0 (0.0)
	Week 12	28 (8.0)	21 (6.0)	7 (2.0)	41 (11.8)	40 (11.5)	1 (0.3)	0 (0.0)	32 (9.3)	25 (7.3)	7 (2.0)	49 (14.2)	49 (14.2)	0 (0.0)	0 (0.0)
	Week 16	35 (10.1)	29 (8.3)	6 (1.7)	46 (13.2)	46 (13.2)	0 (0.0)	0 (0.0)	31 (9.0)	27 (7.8)	4 (1.2)	60 (17.4)	59 (17.2)	1 (0.3)	0 (0.0)
	Week 20	37 (10.6)	35 (10.1)	2 (0.6)	56 (16.1)	55 (15.8)	1 (0.3)	0 (0.0)	41 (11.9)	36 (10.5)	5 (1.5)	63 (18.3)	62 (18.0)	1 (0.3)	0 (0.0)
	Week 24	40 (11.5)	38 (10.9)	2 (0.6)	68 (19.5)	65 (18.7)	3 (0.9)	0 (0.0)	37 (10.8)	35 (10.2)	2 (0.6)	73 (21.2)	72 (20.9)	1 (0.3)	0 (0.0)

N: Number of subjects, COVID: Corona Virus Disease, EASI: Eczema Area and Severity Index, BSA: Body Surface Area, HN-PGIS: Head and Neck - Patient Global Impression of Severity
COVID summarizes the number of subjects with missing data due to COVID-19 infection or logistical restriction, No-COVID summarizes all other subjects with missing data.
topical summarizes the number of rescued subjects of the following categories: plain topical corticosteroids, high/medium/low potency topical corticosteroids, topical calcineurin inhibitor, other topical therapy
systemic summarizes the number of rescued subjects of the following categories: biologic systemic therapy, non-biologic immunomodulating systemic therapy, other systemic therapy
photo summarizes the number of rescued subjects with phototherapy.

Table 2.1.1
Descriptive Statistics for Mean Values and Change from Baseline - Eczema Area and Severity Index (EASI)
(ITT Population)

	Upadacitinib(N=348)					Dupilumab(N=344)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	348	0 (0.0)	30.75 (12.54)			344	0 (0.0)	28.81 (11.51)		
Week 1	325	23 (6.6)	17.36 (11.72)	325	-13.44 (10.24)	319	25 (7.3)	22.34 (12.35)	319	-6.63 (8.09)
Week 2	338	10 (2.9)	10.68 (9.43)	338	-20.37 (11.82)	336	8 (2.3)	15.81 (11.09)	336	-13.09 (9.77)
Week 4	339	9 (2.6)	6.23 (7.22)	339	-24.71 (12.20)	331	13 (3.8)	10.56 (8.44)	331	-18.41 (10.16)
Week 8	338	10 (2.9)	4.21 (6.11)	338	-26.60 (12.51)	325	19 (5.5)	7.33 (7.51)	325	-21.73 (11.10)
Week 12	329	19 (5.5)	3.31 (5.26)	329	-27.34 (12.88)	325	19 (5.5)	5.79 (6.37)	325	-23.32 (11.66)
Week 16	321	27 (7.8)	2.79 (4.56)	321	-27.83 (12.73)	318	26 (7.6)	4.72 (5.54)	318	-24.51 (11.24)
Week 20	321	27 (7.8)	3.10 (6.36)	321	-27.42 (13.03)	311	33 (9.6)	4.16 (5.37)	311	-25.08 (11.61)
Week 24	312	36 (10.3)	2.88 (5.22)	312	-27.43 (13.09)	313	31 (9.0)	3.68 (4.66)	313	-25.51 (11.30)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.

Table 2.1.2
Descriptive Statistics for Mean Values and Change from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT Population)

	Upadacitinib(N=348)					Dupilumab(N=344)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	346	2 (0.6)	7.44 (1.56)			342	2 (0.6)	7.51 (1.68)		
Week 1	341	7 (2.0)	5.02 (2.18)	339	-2.38 (1.93)	340	4 (1.2)	6.70 (1.83)	338	-0.79 (1.33)
Week 2	342	6 (1.7)	3.87 (2.34)	340	-3.53 (2.34)	339	5 (1.5)	5.92 (2.04)	337	-1.58 (1.74)
Week 3	344	4 (1.1)	3.20 (2.32)	342	-4.21 (2.41)	337	7 (2.0)	5.39 (2.19)	335	-2.13 (1.93)
Week 4	340	8 (2.3)	2.90 (2.31)	338	-4.51 (2.44)	332	12 (3.5)	5.00 (2.31)	330	-2.51 (2.08)
Week 5	337	11 (3.2)	2.60 (2.25)	335	-4.81 (2.42)	330	14 (4.1)	4.62 (2.29)	328	-2.90 (2.14)
Week 6	336	12 (3.4)	2.58 (2.31)	334	-4.82 (2.50)	323	21 (6.1)	4.46 (2.31)	321	-3.04 (2.20)
Week 7	334	14 (4.0)	2.51 (2.27)	332	-4.90 (2.49)	325	19 (5.5)	4.26 (2.30)	323	-3.25 (2.24)
Week 8	333	15 (4.3)	2.50 (2.23)	331	-4.91 (2.45)	323	21 (6.1)	4.17 (2.34)	321	-3.34 (2.32)
Week 9	329	19 (5.5)	2.43 (2.25)	327	-4.96 (2.48)	323	21 (6.1)	4.00 (2.27)	321	-3.51 (2.30)
Week 10	328	20 (5.7)	2.44 (2.28)	326	-4.95 (2.51)	324	20 (5.8)	4.00 (2.22)	322	-3.50 (2.33)
Week 11	326	22 (6.3)	2.35 (2.18)	324	-5.02 (2.39)	324	20 (5.8)	3.96 (2.31)	322	-3.57 (2.35)
Week 12	327	21 (6.0)	2.35 (2.15)	325	-5.02 (2.37)	320	24 (7.0)	3.87 (2.28)	318	-3.64 (2.38)
Week 13	326	22 (6.3)	2.33 (2.11)	324	-5.04 (2.37)	320	24 (7.0)	3.75 (2.30)	318	-3.78 (2.37)
Week 14	320	28 (8.0)	2.36 (2.22)	318	-5.00 (2.47)	318	26 (7.6)	3.77 (2.33)	316	-3.74 (2.39)
Week 15	317	31 (8.9)	2.29 (2.19)	315	-5.09 (2.44)	312	32 (9.3)	3.55 (2.30)	310	-3.96 (2.45)
Week 16	309	39 (11.2)	2.23 (2.09)	307	-5.15 (2.44)	304	40 (11.6)	3.53 (2.27)	303	-3.95 (2.47)
Week 18	262	86 (24.7)	2.23 (2.27)	260	-5.16 (2.66)	266	78 (22.7)	3.37 (2.35)	265	-4.17 (2.56)
Week 20	310	38 (10.9)	2.26 (2.49)	308	-5.13 (2.74)	301	43 (12.5)	3.28 (2.33)	300	-4.23 (2.57)
Week 22	299	49 (14.1)	2.14 (2.45)	297	-5.26 (2.79)	290	54 (15.7)	3.17 (2.39)	289	-4.32 (2.70)
Week 24	291	57 (16.4)	2.19 (2.51)	289	-5.15 (2.98)	298	46 (13.4)	3.10 (2.37)	297	-4.38 (2.65)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.

Table 2.1.3
Descriptive Statistics for Mean Values and Change from Baseline - Body Surface Area (BSA)
(ITT Population)

	Upadacitinib(N=348)				Dupilumab(N=344)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n Mean (SD)	n	n_miss (%)	Mean (SD)	n Mean (SD)
Baseline	348	0 (0.0)	48.20 (23.96)		344	0 (0.0)	44.41 (22.83)	
Week 1	325	23 (6.6)	33.60 (24.19)	325 -14.95 (17.26)	319	25 (7.3)	39.43 (23.68)	319 -5.17 (10.02)
Week 2	338	10 (2.9)	23.10 (21.69)	338 -25.56 (20.14)	337	7 (2.0)	31.79 (22.74)	337 -12.79 (14.64)
Week 4	339	9 (2.6)	14.38 (17.41)	339 -34.23 (22.06)	331	13 (3.8)	23.26 (20.35)	331 -21.57 (16.78)
Week 8	337	11 (3.2)	8.98 (13.42)	337 -39.32 (22.77)	324	20 (5.8)	16.05 (17.53)	324 -29.32 (20.72)
Week 12	330	18 (5.2)	7.56 (12.40)	330 -40.43 (23.61)	325	19 (5.5)	12.02 (14.13)	325 -33.13 (21.44)
Week 16	321	27 (7.8)	6.06 (10.45)	321 -41.71 (23.30)	317	27 (7.8)	10.07 (12.77)	317 -35.32 (21.40)
Week 20	321	27 (7.8)	6.49 (12.92)	321 -41.37 (23.55)	311	33 (9.6)	8.96 (11.93)	311 -36.63 (21.68)
Week 24	312	36 (10.3)	6.05 (11.69)	312 -41.40 (23.54)	313	31 (9.0)	7.83 (11.16)	313 -37.50 (21.37)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.

Table 2.1.4
Descriptive Statistics for Mean Values and Change from Baseline - Head and Neck - Patient Global Impression of Severity (HN-PGIS)
(ITT Population)

	Upadacitinib(N=348)					Dupilumab(N=344)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	348	0 (0.0)	3.79 (1.60)			341	3 (0.9)	3.95 (1.46)		
Week 1	315	33 (9.5)	2.10 (1.42)	315	-1.67 (1.53)	315	29 (8.4)	3.24 (1.43)	314	-0.69 (1.30)
Week 2	335	13 (3.7)	1.61 (1.26)	335	-2.16 (1.60)	327	17 (4.9)	2.70 (1.37)	326	-1.24 (1.36)
Week 4	330	18 (5.2)	1.45 (1.34)	330	-2.37 (1.81)	325	19 (5.5)	2.34 (1.39)	322	-1.61 (1.46)
Week 8	327	21 (6.0)	1.41 (1.34)	327	-2.39 (1.79)	314	30 (8.7)	2.08 (1.31)	312	-1.88 (1.58)
Week 12	319	29 (8.3)	1.39 (1.38)	319	-2.39 (1.86)	312	32 (9.3)	1.96 (1.37)	309	-2.04 (1.58)
Week 16	313	35 (10.1)	1.31 (1.32)	313	-2.46 (1.84)	312	32 (9.3)	1.91 (1.37)	309	-2.04 (1.66)
Week 20	310	38 (10.9)	1.27 (1.37)	310	-2.51 (1.81)	302	42 (12.2)	1.75 (1.36)	299	-2.21 (1.67)
Week 24	305	43 (12.4)	1.33 (1.35)	305	-2.47 (1.81)	306	38 (11.0)	1.65 (1.28)	303	-2.29 (1.61)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.

Table 2.2.1
Mixed Effects Model with Repeated Measure for Changes from Baseline - Eczema Area and Severity Index (EASI)
(ITT Population)

	Upadacitinib(N=348)			Dupilumab(N=344)			Difference of					
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)	LSMeans (95% CI)			p-Value	Hedges` g (95% CI)	p-Value
Week 1			-12.52 (0.59)			-7.44 (0.59)	-5.09 (	-6.72,	-3.45)			
Week 2			-19.44 (0.51)			-13.98 (0.51)	-5.46 (	-6.87,	-4.05)			
Week 4			-23.82 (0.39)			-19.16 (0.39)	-4.66 (	-5.74,	-3.57)			
Week 8			-25.80 (0.35)			-22.43 (0.36)	-3.37 (	-4.36,	-2.38)			
Week 12			-26.67 (0.31)			-23.98 (0.32)	-2.69 (	-3.57,	-1.81)			
Week 16			-27.08 (0.28)			-25.11 (0.28)	-1.97 (	-2.74,	-1.20)			
Week 20			-26.76 (0.32)			-25.67 (0.33)	-1.09 (	-1.99,	-0.19)			
Week 24			-26.80 (0.29)			-26.15 (0.29)	-0.65 (	-1.46,	0.15)			
Overall up to Week 24	347	1	-23.61 (0.28)	341	3	-20.49 (0.28)	-3.12 (	-3.89,	-2.35)	<.0001	-0.61 (-0.76, -0.45)	<.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.

Table 2.2.2
Mixed Effects Model with Repeated Measure for Changes from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT Population)

	Upadacitinib(N=348)			Dupilumab(N=344)			Difference of					
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)	LSMeans (95% CI)			p-Value	Hedges` g (95% CI)	p-Value
Week 1			-2.38 (0.09)			-0.78 (0.09)	-1.60 (	-1.85,	-1.36)			
Week 2			-3.51 (0.11)			-1.58 (0.11)	-1.93 (	-2.23,	-1.63)			
Week 3			-4.21 (0.11)			-2.11 (0.11)	-2.09 (	-2.40,	-1.78)			
Week 4			-4.48 (0.12)			-2.49 (0.12)	-2.00 (	-2.32,	-1.67)			
Week 5			-4.77 (0.12)			-2.84 (0.12)	-1.93 (	-2.26,	-1.61)			
Week 6			-4.79 (0.12)			-2.95 (0.12)	-1.84 (	-2.18,	-1.51)			
Week 7			-4.86 (0.12)			-3.18 (0.12)	-1.68 (	-2.02,	-1.34)			
Week 8			-4.87 (0.12)			-3.26 (0.12)	-1.61 (	-1.95,	-1.27)			
Week 9			-4.94 (0.12)			-3.43 (0.12)	-1.51 (	-1.85,	-1.18)			
Week 10			-4.95 (0.12)			-3.44 (0.12)	-1.51 (	-1.85,	-1.18)			
Week 11			-5.01 (0.12)			-3.49 (0.12)	-1.52 (	-1.85,	-1.18)			
Week 12			-5.01 (0.12)			-3.60 (0.12)	-1.41 (	-1.75,	-1.08)			
Week 13			-5.03 (0.12)			-3.71 (0.12)	-1.32 (	-1.65,	-0.98)			
Week 14			-4.99 (0.12)			-3.66 (0.12)	-1.33 (	-1.67,	-0.98)			
Week 15			-5.08 (0.12)			-3.88 (0.12)	-1.20 (	-1.55,	-0.86)			
Week 16			-5.09 (0.12)			-3.87 (0.12)	-1.22 (	-1.56,	-0.88)			
Week 18			-5.07 (0.13)			-4.08 (0.13)	-0.98 (	-1.35,	-0.61)			
Week 20			-5.06 (0.14)			-4.18 (0.14)	-0.88 (	-1.26,	-0.51)			
Week 22			-5.13 (0.14)			-4.28 (0.14)	-0.86 (	-1.25,	-0.47)			
Week 24			-5.02 (0.14)			-4.34 (0.14)	-0.68 (	-1.08,	-0.28)			
Overall up to Week 24	346	2	-4.71 (0.10)	340	4	-3.26 (0.10)	-1.46 (	-1.74,	-1.17)	<.0001	-0.76 (-0.92, -0.61)	<.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.

Table 2.2.3
Mixed Effects Model with Repeated Measure for Changes from Baseline - Body Surface Area (BSA)
(ITT Population)

	Upadacitinib(N=348)			Dupilumab(N=344)			Difference of		
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges` g (95% CI) p-Value
Week 1			-13.42 (0.95)			-6.39 (0.96)	-7.04 (-9.69, -4.38)		
Week 2			-24.38 (0.93)			-14.16 (0.93)	-10.22 (-12.81, -7.64)		
Week 4			-33.00 (0.83)			-22.70 (0.84)	-10.30 (-12.63, -7.97)		
Week 8			-38.24 (0.77)			-30.05 (0.78)	-8.19 (-10.35, -6.03)		
Week 12			-39.63 (0.72)			-33.95 (0.73)	-5.68 (-7.68, -3.67)		
Week 16			-40.68 (0.66)			-36.02 (0.67)	-4.66 (-6.52, -2.80)		
Week 20			-40.37 (0.70)			-37.12 (0.71)	-3.24 (-5.20, -1.28)		
Week 24			-40.47 (0.67)			-38.32 (0.67)	-2.15 (-4.01, -0.28)		
Overall up to Week 24	347	1	-33.77 (0.56)	341	3	-27.34 (0.56)	-6.43 (-8.00, -4.87)	<.0001	-0.62 (-0.77, -0.46) <.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.

Table 2.2.4
Mixed Effects Model with Repeated Measure for Changes from Baseline - Head and Neck - Patient Global Impression of Severity (HN-PGIS)
(ITT Population)

	Upadacitinib(N=348)			Dupilumab(N=344)			Difference of					
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)	LSMeans (95% CI)			p-Value	Hedges` g (95% CI)			p-Value
Week 1			-1.74 (0.07)			-0.66 (0.07)	-1.08 (| -1.27, | -0.89)					
Week 2			-2.21 (0.06)			-1.18 (0.06)	-1.03 (| -1.21, | -0.85)					
Week 4			-2.38 (0.07)			-1.56 (0.07)	-0.82 (| -1.02, | -0.63)					
Week 8			-2.43 (0.07)			-1.78 (0.07)	-0.66 (| -0.85, | -0.46)					
Week 12			-2.45 (0.07)			-1.93 (0.07)	-0.52 (| -0.72, | -0.31)					
Week 16			-2.50 (0.07)			-1.99 (0.07)	-0.51 (| -0.71, | -0.30)					
Week 20			-2.52 (0.07)			-2.15 (0.08)	-0.38 (| -0.59, | -0.17)					
Week 24			-2.45 (0.07)			-2.22 (0.07)	-0.23 (| -0.43, | -0.02)					
Overall up to Week 24	346	2	-2.34 (0.05)	338	6	-1.68 (0.05)	-0.65 (	-0.80,	-0.50)	<.0001	-0.66 (	-0.81,	-0.50)	<.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.

Table 2.3.1
Eczema Area and Severity Index (EASI) 75 response (modified NRI-C)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	56 (16.1)	20 (5.8)
	Number of imputations (NRI), n (%)	10 (2.9)	8 (2.3)
	Number of imputations due to COVID-19 (MI), n (%)	13 (3.7)	17 (4.9)
Week 2	Number of subjects with Response, n (%)	152 (43.8)	62 (18.1)
	Number of imputations (NRI), n (%)	7 (2.0)	5 (1.5)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	3 (0.9)
Week 4	Number of subjects with Response, n (%)	246 (70.6)	127 (37.0)
	Number of imputations (NRI), n (%)	2 (0.6)	11 (3.2)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	2 (0.6)
Week 8	Number of subjects with Response, n (%)	286 (82.2)	203 (59.0)
	Number of imputations (NRI), n (%)	5 (1.4)	13 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	5 (1.4)	6 (1.7)
Week 12	Number of subjects with Response, n (%)	289 (83.0)	227 (66.0)
	Number of imputations (NRI), n (%)	12 (3.4)	14 (4.1)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	5 (1.5)
Week 16	Number of subjects with Response, n (%)	288 (82.7)	255 (74.3)
	Number of imputations (NRI), n (%)	20 (5.7)	22 (6.4)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	4 (1.2)
Week 20	Number of subjects with Response, n (%)	285 (81.9)	261 (75.9)
	Number of imputations (NRI), n (%)	24 (6.9)	26 (7.6)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	7 (2.0)
Week 24	Number of subjects with Response, n (%)	277 (79.6)	263 (76.4)
	Number of imputations (NRI), n (%)	33 (9.5)	29 (8.4)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	2 (0.6)
	Adjusted Analysis		
	Odds Ratio	1.207	
	95% CI	0.841, 1.732	
	p-value	0.3081	
	Relative Risk	1.043	
	95% CI	0.963, 1.129	
	p-value	0.3034	
	Risk Difference	0.032	
	95% CI	-0.029, 0.094	
	p-value	0.3041	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.3.1.1
Eczema Area and Severity Index (EASI) 75 response (modified NRI-C) - Subgroup analysis
(ITT Population)

Visit	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Adjusted Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Week 24	Age						0.1775
	< 40 years	188/ 228 (82.5)	172/ 226 (76.1)	1.084	(0.986, 1.192)	0.0938	
	>= 40 years	89/ 120 (74.2)	91/ 118 (77.0)	0.963	(0.833, 1.113)	0.6071	
	Geographic regions						0.4495
	US/PR/Canada	105/ 140 (74.8)	90/ 131 (68.5)	1.091	(0.938, 1.269)	0.2568	
	Other	172/ 208 (82.9)	173/ 213 (81.2)	1.020	(0.933, 1.116)	0.6634	
	Baseline EASI						0.1601
	< Median (26.4)	132/ 165 (80.2)	131/ 180 (72.8)	1.102	(0.980, 1.240)	0.1039	
	>= Median (26.4)	145/ 183 (79.1)	132/ 164 (80.4)	0.984	(0.885, 1.094)	0.7648	
	Baseline vIGA-AD						0.4342
	3 (Moderate)	141/ 174 (81.1)	129/ 171 (75.4)	1.076	(0.961, 1.204)	0.2029	
	4 (Severe)	136/ 174 (78.1)	134/ 173 (77.4)	1.010	(0.902, 1.130)	0.8680	
	Sex						0.4186
	Female	125/ 165 (75.8)	113/ 150 (75.3)	1.006	(0.887, 1.142)	0.9242	
	Male	152/ 183 (83.1)	150/ 194 (77.2)	1.076	(0.973, 1.190)	0.1559	
	BMI						0.6616
	< 25 kg/m2	133/ 161 (82.7)	139/ 169 (82.2)	1.005	(0.909, 1.111)	0.9243	
	>= 25 - < 30 kg/m2	70/ 93 (75.3)	77/ 110 (69.8)	1.078	(0.910, 1.277)	0.3851	
	>= 30 kg/m2	73/ 93 (78.5)	47/ 65 (72.3)	1.086	(0.903, 1.305)	0.3825	
	Race						0.4811
	White	186/ 235 (79.1)	187/ 244 (76.6)	1.033	(0.939, 1.137)	0.5039	
	Asian	65/ 77 (84.9)	59/ 78 (75.5)	1.124	(0.959, 1.317)	0.1482	
	Other	26/ 36 (71.5)	17/ 22 (77.3)	0.925	(0.679, 1.259)	0.6200	
	Baseline hsCRP						0.4730
	< Median (1.745)	131/ 161 (81.4)	148/ 185 (79.9)	1.019	(0.918, 1.130)	0.7293	
	>= Median(1.745)	146/ 187 (78.1)	115/ 159 (72.3)	1.080	(0.955, 1.221)	0.2185	
	Previous systemic therapy						0.3292
	With	144/ 180 (80.2)	140/ 175 (79.9)	1.003	(0.904, 1.113)	0.9511	
	Without	133/ 168 (79.0)	123/ 169 (72.7)	1.086	(0.962, 1.226)	0.1810	

N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19. Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response n is displayed as integer. Percentages for the response rate n/N are based on the exact value for number of subjects with response n after imputation.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment as covariate and log-link.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 2.3.2
Eczema Area and Severity Index (EASI) 90 response (modified NRI-C)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	18 (5.2)	7 (2.1)
	Number of imputations (NRI), n (%)	10 (2.9)	8 (2.3)
	Number of imputations due to COVID-19 (MI), n (%)	13 (3.7)	17 (4.9)
Week 2	Number of subjects with Response, n (%)	64 (18.4)	20 (5.8)
	Number of imputations (NRI), n (%)	7 (2.0)	5 (1.5)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	3 (0.9)
Week 4	Number of subjects with Response, n (%)	151 (43.5)	51 (14.8)
	Number of imputations (NRI), n (%)	2 (0.6)	11 (3.2)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	2 (0.6)
Week 8	Number of subjects with Response, n (%)	214 (61.5)	100 (29.2)
	Number of imputations (NRI), n (%)	5 (1.4)	13 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	5 (1.4)	6 (1.7)
Week 12	Number of subjects with Response, n (%)	230 (66.0)	141 (40.8)
	Number of imputations (NRI), n (%)	12 (3.4)	14 (4.1)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	5 (1.5)
Week 16	Number of subjects with Response, n (%)	235 (67.5)	154 (44.9)
	Number of imputations (NRI), n (%)	20 (5.7)	22 (6.4)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	4 (1.2)
Week 20	Number of subjects with Response, n (%)	235 (67.5)	169 (49.0)
	Number of imputations (NRI), n (%)	24 (6.9)	26 (7.6)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	7 (2.0)
Week 24	Number of subjects with Response, n (%)	227 (65.3)	197 (57.3)
	Number of imputations (NRI), n (%)	33 (9.5)	29 (8.4)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	2 (0.6)
	Adjusted Analysis		
	Odds Ratio	1.403	
	95% CI	1.030, 1.911	
	p-value	0.0315	
	Relative Risk	1.137	
	95% CI	1.009, 1.282	
	p-value	0.0344	
	Risk Difference	0.080	
	95% CI	0.007, 0.152	
	p-value	0.0315	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.3.2.1
Eczema Area and Severity Index (EASI) 90 response (modified NRI-C) - Subgroup analysis
(ITT Population)

Visit	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Adjusted Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Week 24	Age						0.3906
	< 40 years	150/ 228 (65.9)	136/ 226 (60.0)	1.099	(0.953, 1.267)	0.1959	
	>= 40 years	77/ 120 (64.2)	62/ 118 (52.1)	1.231	(0.989, 1.533)	0.0630	
	Geographic regions						0.2145
	US/PR/Canada	89/ 140 (63.8)	66/ 131 (50.4)	1.266	(1.024, 1.565)	0.0292	
	Other	138/ 208 (66.3)	131/ 213 (61.5)	1.078	(0.933, 1.245)	0.3086	
	Baseline EASI						0.9421
	< Median (26.4)	105/ 165 (63.7)	101/ 180 (56.1)	1.136	(0.955, 1.350)	0.1503	
	>= Median (26.4)	122/ 183 (66.7)	96/ 164 (58.5)	1.139	(0.965, 1.345)	0.1232	
	Baseline vIGA-AD						0.6061
	3 (Moderate)	116/ 174 (66.9)	104/ 171 (60.5)	1.106	(0.942, 1.298)	0.2201	
	4 (Severe)	111/ 174 (63.6)	94/ 173 (54.0)	1.178	(0.985, 1.407)	0.0724	
	Sex						0.8112
	Female	106/ 165 (64.3)	86/ 150 (57.3)	1.122	(0.938, 1.342)	0.2071	
	Male	121/ 183 (66.1)	111/ 194 (57.2)	1.156	(0.984, 1.357)	0.0772	
	BMI						0.1982
	< 25 kg/m2	107/ 161 (66.6)	105/ 169 (62.1)	1.071	(0.912, 1.259)	0.4022	
	>= 25 - < 30 kg/m2	53/ 93 (57.0)	59/ 110 (53.6)	1.063	(0.828, 1.363)	0.6327	
	>= 30 kg/m2	66/ 93 (71.0)	33/ 65 (50.8)	1.398	(1.065, 1.836)	0.0160	
	Race						0.0826
	White	151/ 235 (64.1)	149/ 244 (60.9)	1.054	(0.917, 1.211)	0.4593	
	Asian	56/ 77 (72.9)	41/ 78 (51.9)	1.404	(1.088, 1.812)	0.0091	
	Other	20/ 36 (56.4)	8/ 22 (36.4)	1.550	(0.830, 2.895)	0.1689	
	Baseline hsCRP						0.4043
	< Median (1.745)	103/ 161 (64.2)	110/ 185 (59.2)	1.085	(0.919, 1.282)	0.3351	
	>= Median(1.745)	124/ 187 (66.2)	88/ 159 (55.0)	1.202	(1.010, 1.432)	0.0387	
	Previous systemic therapy						0.2813
	With	116/ 180 (64.5)	106/ 175 (60.3)	1.070	(0.910, 1.259)	0.4125	
	Without	111/ 168 (66.1)	92/ 169 (54.1)	1.221	(1.023, 1.456)	0.0269	

N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19. Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response n is displayed as integer. Percentages for the response rate n/N are based on the exact value for number of subjects with response n after imputation.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment as covariate and log-link.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 2.3.3
Eczema Area and Severity Index (EASI) 100 response (modified NRI-C)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	2 (0.6)	1 (0.3)
	Number of imputations (NRI), n (%)	10 (2.9)	8 (2.3)
	Number of imputations due to COVID-19 (MI), n (%)	13 (3.7)	17 (4.9)
Week 2	Number of subjects with Response, n (%)	10 (2.9)	3 (0.9)
	Number of imputations (NRI), n (%)	7 (2.0)	5 (1.5)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	3 (0.9)
Week 4	Number of subjects with Response, n (%)	29 (8.3)	6 (1.7)
	Number of imputations (NRI), n (%)	2 (0.6)	11 (3.2)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	2 (0.6)
Week 8	Number of subjects with Response, n (%)	57 (16.4)	14 (4.1)
	Number of imputations (NRI), n (%)	5 (1.4)	13 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	5 (1.4)	6 (1.7)
Week 12	Number of subjects with Response, n (%)	77 (22.1)	26 (7.6)
	Number of imputations (NRI), n (%)	12 (3.4)	14 (4.1)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	5 (1.5)
Week 16	Number of subjects with Response, n (%)	103 (29.6)	28 (8.2)
	Number of imputations (NRI), n (%)	20 (5.7)	22 (6.4)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	4 (1.2)
Week 20	Number of subjects with Response, n (%)	104 (29.9)	36 (10.5)
	Number of imputations (NRI), n (%)	24 (6.9)	26 (7.6)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	7 (2.0)
Week 24	Number of subjects with Response, n (%)	100 (28.7)	48 (14.0)
	Number of imputations (NRI), n (%)	33 (9.5)	29 (8.4)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	2 (0.6)
	Adjusted Analysis		
	Odds Ratio	2.508	
	95% CI	1.706, 3.686	
	p-value	<.0001	
	Relative Risk	2.049	
	95% CI	1.505, 2.791	
	p-value	<.0001	
	Risk Difference	0.146	
	95% CI	0.087, 0.206	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.3.3.1
Eczema Area and Severity Index (EASI) 100 response (modified NRI-C) - Subgroup analysis
(ITT Population)

Visit	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Adjusted Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Week 24	Age						0.6679
	< 40 years	59/ 228 (25.9)	30/ 226 (13.3)	1.951	(1.309, 2.907)	0.0010	
	>= 40 years	41/ 120 (34.2)	18/ 118 (15.3)	2.240	(1.369, 3.665)	0.0013	
	Geographic regions						0.7126
	US/PR/Canada	51/ 140 (36.4)	22/ 131 (16.8)	2.169	(1.398, 3.366)	0.0006	
	Other	49/ 208 (23.6)	26/ 213 (12.2)	1.931	(1.249, 2.985)	0.0031	
	Baseline EASI						0.8812
	< Median (26.4)	59/ 165 (35.8)	30/ 180 (16.7)	2.145	(1.459, 3.154)	0.0001	
	>= Median (26.4)	41/ 183 (22.4)	18/ 164 (11.0)	2.043	(1.224, 3.411)	0.0063	
	Baseline vIGA-AD						0.5378
	3 (Moderate)	58/ 174 (33.3)	30/ 171 (17.5)	1.900	(1.290, 2.798)	0.0011	
	4 (Severe)	42/ 174 (24.2)	18/ 173 (10.4)	2.322	(1.394, 3.868)	0.0012	
	Sex						0.8909
	Female	59/ 165 (35.8)	26/ 150 (17.3)	2.064	(1.377, 3.094)	0.0005	
	Male	41/ 183 (22.4)	22/ 194 (11.3)	1.976	(1.226, 3.183)	0.0051	
	BMI						0.9821
	< 25 kg/m2	48/ 161 (29.8)	25/ 169 (14.8)	2.017	(1.309, 3.108)	0.0015	
	>= 25 - < 30 kg/m2	24/ 93 (25.8)	14/ 110 (12.7)	2.028	(1.114, 3.689)	0.0206	
	>= 30 kg/m2	28/ 93 (30.1)	9/ 65 (13.8)	2.174	(1.101, 4.296)	0.0254	
	Race						0.1444
	White	70/ 235 (29.8)	41/ 244 (16.8)	1.774	(1.261, 2.495)	0.0010	
	Asian	23/ 77 (29.9)	6/ 78 (7.7)	3.883	(1.674, 9.008)	0.0016	
	Other	7/ 36 (19.4)	1/ 22 (4.5)	4.278	(0.563, 32.475)	0.1599	
	Baseline hsCRP						0.1865
	< Median (1.745)	49/ 161 (30.4)	32/ 185 (17.3)	1.760	(1.189, 2.604)	0.0047	
	>= Median(1.745)	51/ 187 (27.3)	16/ 159 (10.1)	2.712	(1.612, 4.563)	0.0002	
	Previous systemic therapy						0.2613
	With	42/ 180 (23.3)	24/ 175 (13.7)	1.701	(1.078, 2.685)	0.0225	
	Without	58/ 168 (34.5)	24/ 169 (14.2)	2.432	(1.590, 3.721)	<.0001	

N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19. Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response n is displayed as integer. Percentages for the response rate n/N are based on the exact value for number of subjects with response n after imputation.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment as covariate and log-link.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	75 (21.6)	8 (2.3)
	Number of imputations (NRI), n (%)	7 (2.0)	3 (0.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	1 (0.3)
Week 2	Number of subjects with Response, n (%)	158 (45.4)	35 (10.3)
	Number of imputations (NRI), n (%)	5 (1.4)	4 (1.2)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 3	Number of subjects with Response, n (%)	192 (55.1)	58 (16.9)
	Number of imputations (NRI), n (%)	3 (0.9)	6 (1.7)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 4	Number of subjects with Response, n (%)	208 (59.8)	77 (22.5)
	Number of imputations (NRI), n (%)	7 (2.0)	11 (3.2)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 5	Number of subjects with Response, n (%)	227 (65.2)	97 (28.3)
	Number of imputations (NRI), n (%)	10 (2.9)	13 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 6	Number of subjects with Response, n (%)	226 (64.9)	105 (30.7)
	Number of imputations (NRI), n (%)	11 (3.2)	20 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 7	Number of subjects with Response, n (%)	225 (64.6)	119 (34.7)
	Number of imputations (NRI), n (%)	13 (3.7)	18 (5.2)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 8	Number of subjects with Response, n (%)	224 (64.3)	122 (35.6)
	Number of imputations (NRI), n (%)	14 (4.0)	20 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 9	Number of subjects with Response, n (%)	226 (64.9)	135 (39.1)
	Number of imputations (NRI), n (%)	18 (5.2)	20 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 10	Number of subjects with Response, n (%)	231 (66.4)	126 (36.5)
	Number of imputations (NRI), n (%)	18 (5.2)	19 (5.5)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 11	Number of subjects with Response, n (%)	224 (64.3)	134 (38.8)
	Number of imputations (NRI), n (%)	20 (5.7)	19 (5.5)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 12	Number of subjects with Response, n (%)	225 (64.6)	140 (40.6)
	Number of imputations (NRI), n (%)	19 (5.5)	23 (6.7)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 13	Number of subjects with Response, n (%)	230 (66.0)	136 (39.4)
	Number of imputations (NRI), n (%)	20 (5.7)	23 (6.7)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 14	Number of subjects with Response, n (%)	223 (64.0)	136 (39.4)
	Number of imputations (NRI), n (%)	26 (7.5)	25 (7.3)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 15	Number of subjects with Response, n (%)	221 (63.4)	152 (44.1)
	Number of imputations (NRI), n (%)	29 (8.3)	31 (9.0)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 16	Number of subjects with Response, n (%)	219 (62.8)	152 (44.1)
	Number of imputations (NRI), n (%)	37 (10.6)	39 (11.3)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 18	Number of subjects with Response, n (%)	221 (63.4)	165 (47.8)
	Number of imputations (NRI), n (%)	80 (23.0)	73 (21.2)
	Number of imputations due to COVID-19 (MI), n (%)	6 (1.7)	5 (1.5)
Week 20	Number of subjects with Response, n (%)	228 (65.4)	169 (49.1)
	Number of imputations (NRI), n (%)	36 (10.3)	39 (11.3)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	4 (1.2)
Week 22	Number of subjects with Response, n (%)	226 (64.8)	176 (51.1)
	Number of imputations (NRI), n (%)	45 (12.9)	50 (14.5)
	Number of imputations due to COVID-19 (MI), n (%)	4 (1.1)	4 (1.2)
Week 24	Number of subjects with Response, n (%)	212 (60.8)	178 (51.7)
	Number of imputations (NRI), n (%)	55 (15.8)	45 (13.1)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
	Adjusted Analysis		
	Odds Ratio	1.457	
	95% CI	1.076, 1.972	
	p-value	0.0150	
	Relative Risk	1.175	
	95% CI	1.030, 1.341	
	p-value	0.0165	
	Risk Difference	0.092	
	95% CI	0.018, 0.165	
	p-value	0.0146	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.3.4.1
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C) - Subgroup analysis
(ITT Population)

Visit	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Adjusted Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Week 24	Age						0.9118
	< 40 years	143/ 228 (62.5)	121/ 226 (53.4)	1.171	(1.000, 1.372)	0.0504	
	>= 40 years	69/ 120 (57.5)	57/ 118 (48.3)	1.190	(0.935, 1.516)	0.1579	
	Geographic regions						0.9002
	US/PR/Canada	76/ 140 (54.1)	61/ 131 (46.3)	1.168	(0.919, 1.485)	0.2050	
	Other	136/ 208 (65.3)	117/ 213 (54.9)	1.189	(1.016, 1.391)	0.0308	
	Baseline EASI						0.9134
	< Median (26.4)	95/ 165 (57.5)	89/ 180 (49.4)	1.162	(0.954, 1.417)	0.1359	
	>= Median (26.4)	117/ 183 (63.8)	89/ 164 (54.1)	1.180	(0.987, 1.411)	0.0701	
	Baseline vIGA-AD						0.7237
	3 (Moderate)	100/ 174 (57.2)	81/ 171 (47.4)	1.208	(0.985, 1.482)	0.0688	
	4 (Severe)	112/ 174 (64.4)	97/ 173 (55.9)	1.152	(0.969, 1.369)	0.1093	
	Sex						0.3467
	Female	97/ 165 (58.5)	80/ 150 (53.3)	1.098	(0.901, 1.337)	0.3550	
	Male	115/ 183 (62.8)	98/ 194 (50.4)	1.248	(1.043, 1.492)	0.0153	
	BMI						0.7039
	< 25 kg/m2	106/ 161 (65.6)	90/ 169 (53.3)	1.232	(1.028, 1.475)	0.0237	
	>= 25 - < 30 kg/m2	53/ 93 (57.0)	58/ 110 (52.5)	1.086	(0.845, 1.397)	0.5175	
	>= 30 kg/m2	53/ 93 (57.0)	30/ 65 (46.2)	1.235	(0.900, 1.694)	0.1915	
	Race						0.1691
	White	142/ 235 (60.4)	132/ 244 (54.1)	1.117	(0.956, 1.304)	0.1623	
	Asian	53/ 77 (68.6)	36/ 78 (45.8)	1.499	(1.126, 1.995)	0.0055	
	Other	17/ 36 (46.6)	10/ 22 (45.5)	1.024	(0.574, 1.827)	0.9352	
	Baseline hsCRP						0.7194
	< Median (1.745)	99/ 161 (61.2)	94/ 185 (50.8)	1.205	(0.999, 1.455)	0.0516	
	>= Median(1.745)	113/ 187 (60.4)	84/ 159 (52.6)	1.148	(0.951, 1.385)	0.1502	
	Previous systemic therapy						0.6395
	With	109/ 180 (60.5)	93/ 175 (53.0)	1.141	(0.950, 1.371)	0.1568	
	Without	103/ 168 (61.2)	85/ 169 (50.3)	1.216	(1.003, 1.474)	0.0462	

N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19. Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response n is displayed as integer. Percentages for the response rate n/N are based on the exact value for number of subjects with response n after imputation.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment as covariate and log-link.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	7 (2.0)	3 (0.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	1 (0.3)
Week 2	Number of subjects with Response, n (%)	11 (3.2)	1 (0.3)
	Number of imputations (NRI), n (%)	5 (1.4)	4 (1.2)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 3	Number of subjects with Response, n (%)	16 (4.6)	1 (0.3)
	Number of imputations (NRI), n (%)	3 (0.9)	6 (1.7)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 4	Number of subjects with Response, n (%)	22 (6.3)	3 (0.9)
	Number of imputations (NRI), n (%)	7 (2.0)	11 (3.2)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 5	Number of subjects with Response, n (%)	32 (9.2)	5 (1.5)
	Number of imputations (NRI), n (%)	10 (2.9)	13 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 6	Number of subjects with Response, n (%)	48 (13.8)	4 (1.2)
	Number of imputations (NRI), n (%)	11 (3.2)	20 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 7	Number of subjects with Response, n (%)	51 (14.7)	4 (1.2)
	Number of imputations (NRI), n (%)	13 (3.7)	18 (5.2)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 8	Number of subjects with Response, n (%)	51 (14.7)	7 (2.0)
	Number of imputations (NRI), n (%)	14 (4.0)	20 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 9	Number of subjects with Response, n (%)	53 (15.2)	8 (2.3)
	Number of imputations (NRI), n (%)	18 (5.2)	20 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	1 (0.3)	1 (0.3)
Week 10	Number of subjects with Response, n (%)	48 (13.8)	6 (1.7)
	Number of imputations (NRI), n (%)	18 (5.2)	19 (5.5)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 11	Number of subjects with Response, n (%)	52 (14.9)	9 (2.6)
	Number of imputations (NRI), n (%)	20 (5.7)	19 (5.5)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 12	Number of subjects with Response, n (%)	60 (17.2)	5 (1.5)
	Number of imputations (NRI), n (%)	19 (5.5)	23 (6.7)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 13	Number of subjects with Response, n (%)	60 (17.2)	7 (2.0)
	Number of imputations (NRI), n (%)	20 (5.7)	23 (6.7)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 14	Number of subjects with Response, n (%)	60 (17.2)	8 (2.3)
	Number of imputations (NRI), n (%)	26 (7.5)	25 (7.3)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 15	Number of subjects with Response, n (%)	66 (19.0)	14 (4.1)
	Number of imputations (NRI), n (%)	29 (8.3)	31 (9.0)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 16	Number of subjects with Response, n (%)	63 (18.1)	15 (4.4)
	Number of imputations (NRI), n (%)	37 (10.6)	39 (11.3)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
Week 18	Number of subjects with Response, n (%)	77 (22.1)	25 (7.3)
	Number of imputations (NRI), n (%)	80 (23.0)	73 (21.2)
	Number of imputations due to COVID-19 (MI), n (%)	6 (1.7)	5 (1.5)
Week 20	Number of subjects with Response, n (%)	95 (27.3)	28 (8.1)
	Number of imputations (NRI), n (%)	36 (10.3)	39 (11.3)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	4 (1.2)
Week 22	Number of subjects with Response, n (%)	104 (29.9)	36 (10.5)
	Number of imputations (NRI), n (%)	45 (12.9)	50 (14.5)
	Number of imputations due to COVID-19 (MI), n (%)	4 (1.1)	4 (1.2)
Week 24	Number of subjects with Response, n (%)	92 (26.4)	29 (8.4)
	Number of imputations (NRI), n (%)	55 (15.8)	45 (13.1)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	1 (0.3)
	Adjusted Analysis		
	Odds Ratio	3.905	
	95% CI	2.493, 6.117	
	p-value	<.0001	
	Relative Risk	3.135	
	95% CI	2.123, 4.630	
	p-value	<.0001	
	Risk Difference	0.180	
	95% CI	0.126, 0.235	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.3.5.1
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C) - Subgroup analysis
(ITT Population)

Visit	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Adjusted Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Week 24	Age						0.4060
	< 40 years	58/ 228 (25.4)	16/ 226 (7.1)	3.593	(2.132, 6.056)	<.0001	
	>= 40 years	34/ 120 (28.3)	13/ 118 (11.0)	2.572	(1.431, 4.623)	0.0016	
	Geographic regions						0.5016
	US/PR/Canada	43/ 140 (30.7)	11/ 131 (8.4)	3.658	(1.972, 6.785)	<.0001	
	Other	49/ 208 (23.6)	18/ 213 (8.5)	2.788	(1.682, 4.620)	<.0001	
	Baseline EASI						0.9066
	< Median (26.4)	42/ 165 (25.5)	15/ 180 (8.3)	3.055	(1.762, 5.296)	<.0001	
	>= Median (26.4)	50/ 183 (27.3)	14/ 164 (8.5)	3.201	(1.839, 5.569)	<.0001	
	Baseline vIGA-AD						0.6232
	3 (Moderate)	46/ 174 (26.4)	13/ 171 (7.6)	3.477	(1.950, 6.200)	<.0001	
	4 (Severe)	46/ 174 (26.4)	16/ 173 (9.2)	2.858	(1.685, 4.849)	<.0001	
	Sex						0.8925
	Female	46/ 165 (27.9)	13/ 150 (8.7)	3.217	(1.811, 5.714)	<.0001	
	Male	46/ 183 (25.1)	16/ 194 (8.2)	3.048	(1.791, 5.187)	<.0001	
	BMI						0.2277
	< 25 kg/m2	41/ 161 (25.5)	15/ 169 (8.9)	2.869	(1.654, 4.976)	0.0002	
	>= 25 - < 30 kg/m2	22/ 93 (23.7)	11/ 110 (10.0)	2.366	(1.212, 4.618)	0.0117	
	>= 30 kg/m2	29/ 93 (31.2)	3/ 65 (4.6)	6.756	(2.149, 21.245)	0.0011	
	Race						0.0489
	White	61/ 235 (26.0)	25/ 244 (10.2)	2.533	(1.649, 3.893)	<.0001	
	Asian	20/ 77 (26.0)	4/ 78 (5.1)	5.065	(1.815, 14.135)	0.0019	
	Other	11/ 36 (30.6)	0/ 22 (0.0)	NE	(NE, NE)	NE	
	Baseline hsCRP						0.2619
	< Median (1.745)	40/ 161 (24.8)	18/ 185 (9.7)	2.553	(1.526, 4.272)	0.0004	
	>= Median(1.745)	52/ 187 (27.8)	11/ 159 (6.9)	4.019	(2.173, 7.436)	<.0001	
	Previous systemic therapy						0.6329
	With	44/ 180 (24.4)	15/ 175 (8.6)	2.852	(1.649, 4.932)	0.0002	
	Without	48/ 168 (28.6)	14/ 169 (8.3)	3.449	(1.979, 6.012)	<.0001	

N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19. Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response n is displayed as integer. Percentages for the response rate n/N are based on the exact value for number of subjects with response n after imputation.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment as covariate and log-link.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 2.3.6
Body Surface Area (BSA) = 0 (modified NRI-C)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	2 (0.6)	1 (0.3)
	Number of imputations (NRI), n (%)	10 (2.9)	8 (2.3)
	Number of imputations due to COVID-19 (MI), n (%)	13 (3.7)	17 (4.9)
Week 2	Number of subjects with Response, n (%)	10 (2.9)	3 (0.9)
	Number of imputations (NRI), n (%)	7 (2.0)	4 (1.2)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	3 (0.9)
Week 4	Number of subjects with Response, n (%)	29 (8.3)	6 (1.7)
	Number of imputations (NRI), n (%)	2 (0.6)	11 (3.2)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	2 (0.6)
Week 8	Number of subjects with Response, n (%)	57 (16.4)	14 (4.1)
	Number of imputations (NRI), n (%)	6 (1.7)	14 (4.1)
	Number of imputations due to COVID-19 (MI), n (%)	5 (1.4)	6 (1.7)
Week 12	Number of subjects with Response, n (%)	77 (22.1)	26 (7.6)
	Number of imputations (NRI), n (%)	12 (3.4)	14 (4.1)
	Number of imputations due to COVID-19 (MI), n (%)	6 (1.7)	5 (1.5)
Week 16	Number of subjects with Response, n (%)	104 (29.9)	29 (8.4)
	Number of imputations (NRI), n (%)	20 (5.7)	23 (6.7)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	4 (1.2)
Week 20	Number of subjects with Response, n (%)	105 (30.2)	36 (10.5)
	Number of imputations (NRI), n (%)	24 (6.9)	26 (7.6)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	7 (2.0)
Week 24	Number of subjects with Response, n (%)	100 (28.7)	48 (14.0)
	Number of imputations (NRI), n (%)	33 (9.5)	29 (8.4)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	2 (0.6)
	Adjusted Analysis		
	Odds Ratio	2.506	
	95% CI	1.705, 3.685	
	p-value	<.0001	
	Relative Risk	2.049	
	95% CI	1.504, 2.790	
	p-value	<.0001	
	Risk Difference	0.146	
	95% CI	0.087, 0.205	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.3.6.1
Body Surface Area (BSA) = 0 (modified NRI-C) - Subgroup analysis
(ITT Population)

Visit	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Adjusted Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Week 24	Age						0.6667
	< 40 years	59/ 228 (25.9)	30/ 226 (13.3)	1.949	(1.308, 2.906)	0.0010	
	>= 40 years	41/ 120 (34.2)	18/ 118 (15.3)	2.240	(1.369, 3.665)	0.0013	
	Geographic regions						0.7110
	US/PR/Canada	51/ 140 (36.4)	22/ 131 (16.8)	2.169	(1.398, 3.366)	0.0006	
	Other	49/ 208 (23.6)	26/ 213 (12.2)	1.930	(1.249, 2.983)	0.0031	
	Baseline EASI						0.8792
	< Median (26.4)	59/ 165 (35.8)	30/ 180 (16.7)	2.145	(1.459, 3.154)	0.0001	
	>= Median (26.4)	41/ 183 (22.4)	18/ 164 (11.0)	2.041	(1.223, 3.408)	0.0064	
	Baseline vIGA-AD						0.5394
	3 (Moderate)	58/ 174 (33.3)	30/ 171 (17.5)	1.900	(1.290, 2.798)	0.0011	
	4 (Severe)	42/ 174 (24.1)	18/ 173 (10.4)	2.320	(1.392, 3.865)	0.0012	
	Sex						0.8923
	Female	59/ 165 (35.8)	26/ 150 (17.3)	2.063	(1.376, 3.093)	0.0005	
	Male	41/ 183 (22.4)	22/ 194 (11.3)	1.976	(1.226, 3.183)	0.0051	
	BMI						0.9820
	< 25 kg/m2	48/ 161 (29.8)	25/ 169 (14.8)	2.015	(1.308, 3.106)	0.0015	
	>= 25 - < 30 kg/m2	24/ 93 (25.8)	14/ 110 (12.7)	2.028	(1.114, 3.689)	0.0206	
	>= 30 kg/m2	28/ 93 (30.1)	9/ 65 (13.8)	2.174	(1.101, 4.296)	0.0254	
	Race						0.1440
	White	70/ 235 (29.8)	41/ 244 (16.8)	1.773	(1.260, 2.494)	0.0010	
	Asian	23/ 77 (29.9)	6/ 78 (7.7)	3.883	(1.674, 9.008)	0.0016	
	Other	7/ 36 (19.4)	1/ 22 (4.5)	4.278	(0.563, 32.475)	0.1599	
	Baseline hsCRP						0.1871
	< Median (1.745)	49/ 161 (30.4)	32/ 185 (17.3)	1.760	(1.189, 2.604)	0.0047	
	>= Median(1.745)	51/ 187 (27.3)	16/ 159 (10.1)	2.710	(1.611, 4.560)	0.0002	
	Previous systemic therapy						0.2621
	With	42/ 180 (23.3)	24/ 175 (13.7)	1.701	(1.078, 2.685)	0.0225	
	Without	58/ 168 (34.5)	24/ 169 (14.2)	2.431	(1.589, 3.719)	<.0001	

N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19. Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response n is displayed as integer. Percentages for the response rate n/N are based on the exact value for number of subjects with response n after imputation.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment as covariate and log-link.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 2.3.7
Head and Neck - Patient Global Impression of Severity (HN-PGIS) = 0 (modified NRI-C)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	40 (11.5)	13 (3.9)
	Number of imputations (NRI), n (%)	21 (6.0)	16 (4.7)
	Number of imputations due to COVID-19 (MI), n (%)	12 (3.4)	13 (3.8)
Week 2	Number of subjects with Response, n (%)	65 (18.7)	23 (6.7)
	Number of imputations (NRI), n (%)	10 (2.9)	14 (4.1)
	Number of imputations due to COVID-19 (MI), n (%)	3 (0.9)	3 (0.9)
Week 4	Number of subjects with Response, n (%)	88 (25.1)	30 (8.8)
	Number of imputations (NRI), n (%)	12 (3.4)	15 (4.4)
	Number of imputations due to COVID-19 (MI), n (%)	6 (1.7)	4 (1.2)
Week 8	Number of subjects with Response, n (%)	95 (27.2)	33 (9.7)
	Number of imputations (NRI), n (%)	14 (4.0)	21 (6.1)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	9 (2.6)
Week 12	Number of subjects with Response, n (%)	100 (28.7)	41 (11.9)
	Number of imputations (NRI), n (%)	22 (6.3)	25 (7.3)
	Number of imputations due to COVID-19 (MI), n (%)	7 (2.0)	7 (2.0)
Week 16	Number of subjects with Response, n (%)	107 (30.8)	50 (14.5)
	Number of imputations (NRI), n (%)	29 (8.3)	28 (8.1)
	Number of imputations due to COVID-19 (MI), n (%)	6 (1.7)	4 (1.2)
Week 20	Number of subjects with Response, n (%)	122 (34.9)	56 (16.1)
	Number of imputations (NRI), n (%)	36 (10.3)	37 (10.8)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	5 (1.5)
Week 24	Number of subjects with Response, n (%)	99 (28.5)	58 (16.9)
	Number of imputations (NRI), n (%)	41 (11.8)	36 (10.5)
	Number of imputations due to COVID-19 (MI), n (%)	2 (0.6)	2 (0.6)
	Adjusted Analysis		
	Odds Ratio	1.960	
	95% CI	1.358, 2.828	
	p-value	0.0003	
	Relative Risk	1.692	
	95% CI	1.269, 2.255	
	p-value	0.0003	
	Risk Difference	0.114	
	95% CI	0.051, 0.176	
	p-value	0.0003	

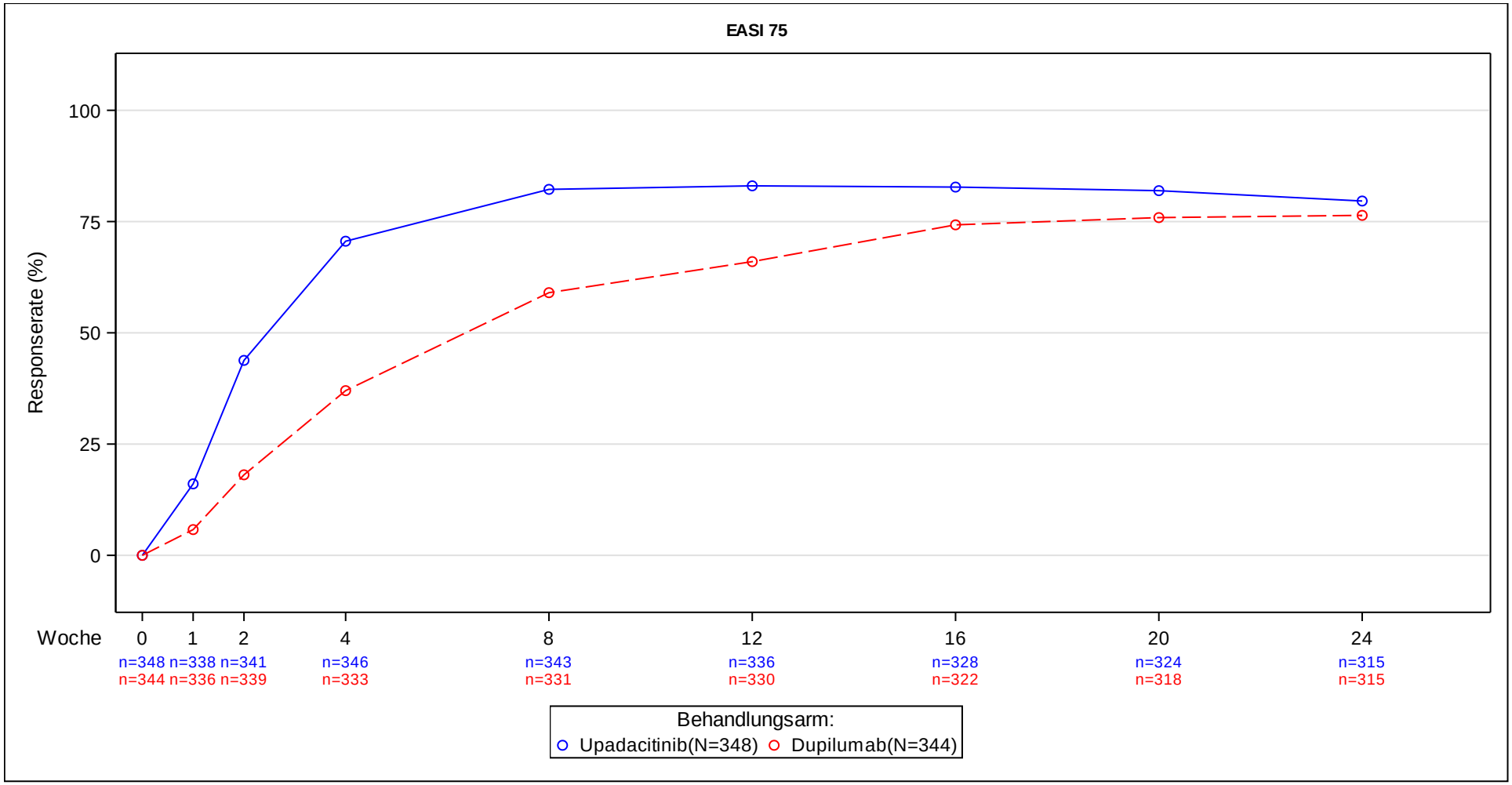
N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.3.7.1
Head and Neck - Patient Global Impression of Severity (HN-PGIS) = 0 (modified NRI-C) - Subgroup analysis
(ITT Population)

Visit	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Adjusted Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Week 24	Age						0.0737
	< 40 years	62/ 228 (27.3)	29/ 226 (12.9)	2.116	(1.418, 3.159)	0.0002	
	>= 40 years	37/ 120 (30.8)	29/ 118 (24.6)	1.252	(0.827, 1.894)	0.2882	
	Geographic regions						0.3383
	US/PR/Canada	52/ 140 (37.3)	25/ 131 (19.3)	1.935	(1.280, 2.924)	0.0017	
	Other	47/ 208 (22.6)	33/ 213 (15.5)	1.462	(0.978, 2.185)	0.0643	
	Baseline EASI						0.9249
	< Median (26.4)	52/ 165 (31.6)	33/ 180 (18.3)	1.722	(1.176, 2.523)	0.0052	
	>= Median (26.4)	47/ 183 (25.8)	25/ 164 (15.4)	1.675	(1.083, 2.593)	0.0206	
	Baseline vIGA-AD						0.2090
	3 (Moderate)	57/ 174 (32.9)	28/ 171 (16.4)	2.005	(1.344, 2.992)	0.0007	
	4 (Severe)	42/ 174 (24.1)	30/ 173 (17.4)	1.384	(0.911, 2.104)	0.1277	
	Sex						0.8125
	Female	53/ 165 (32.3)	28/ 150 (18.7)	1.729	(1.158, 2.582)	0.0074	
	Male	46/ 183 (25.1)	30/ 194 (15.6)	1.613	(1.067, 2.438)	0.0233	
	BMI						0.6896
	< 25 kg/m2	45/ 161 (28.1)	26/ 169 (15.4)	1.827	(1.186, 2.815)	0.0062	
	>= 25 - < 30 kg/m2	22/ 93 (23.7)	19/ 110 (17.5)	1.353	(0.782, 2.341)	0.2791	
	>= 30 kg/m2	32/ 93 (34.4)	13/ 65 (20.0)	1.720	(0.981, 3.016)	0.0582	
	Race						0.5541
	White	68/ 235 (28.9)	46/ 244 (18.9)	1.533	(1.104, 2.129)	0.0108	
	Asian	19/ 77 (24.8)	8/ 78 (10.5)	2.371	(1.105, 5.088)	0.0267	
	Other	12/ 36 (33.8)	4/ 22 (18.2)	1.858	(0.684, 5.047)	0.2244	
	Baseline hsCRP						0.8401
	< Median (1.745)	45/ 161 (28.1)	30/ 185 (16.3)	1.730	(1.147, 2.609)	0.0090	
	>= Median(1.745)	54/ 187 (28.9)	28/ 159 (17.7)	1.630	(1.088, 2.443)	0.0179	
	Previous systemic therapy						0.6452
	With	42/ 180 (23.4)	26/ 175 (15.0)	1.564	(1.005, 2.435)	0.0476	
	Without	57/ 168 (34.0)	32/ 169 (19.0)	1.793	(1.231, 2.614)	0.0024	

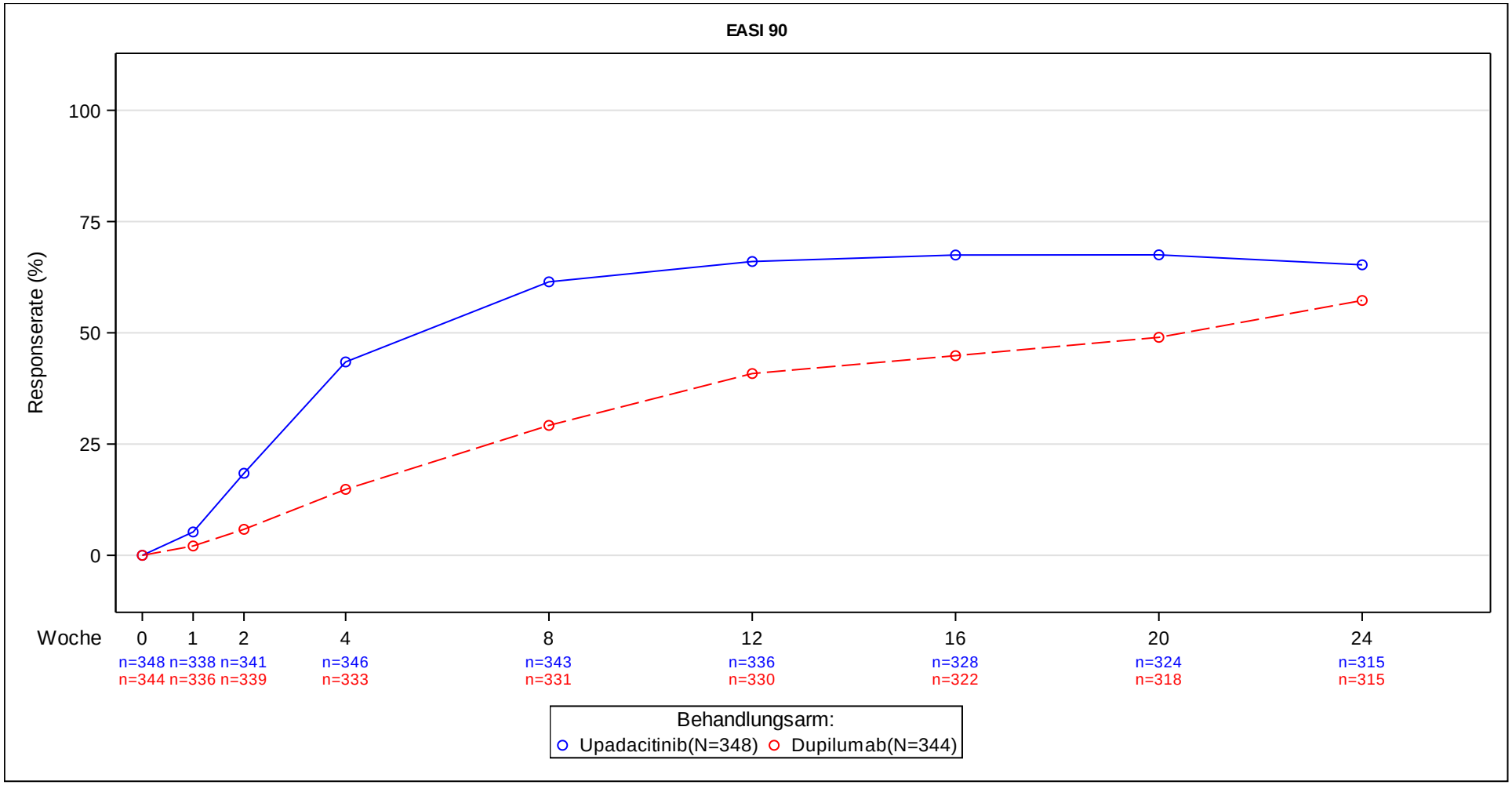
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19. Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response n is displayed as integer. Percentages for the response rate n/N are based on the exact value for number of subjects with response n after imputation.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment as covariate and log-link.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Figure 2.4.1
Eczema Area and Severity Index (EASI) 75 response
(ITT Population)



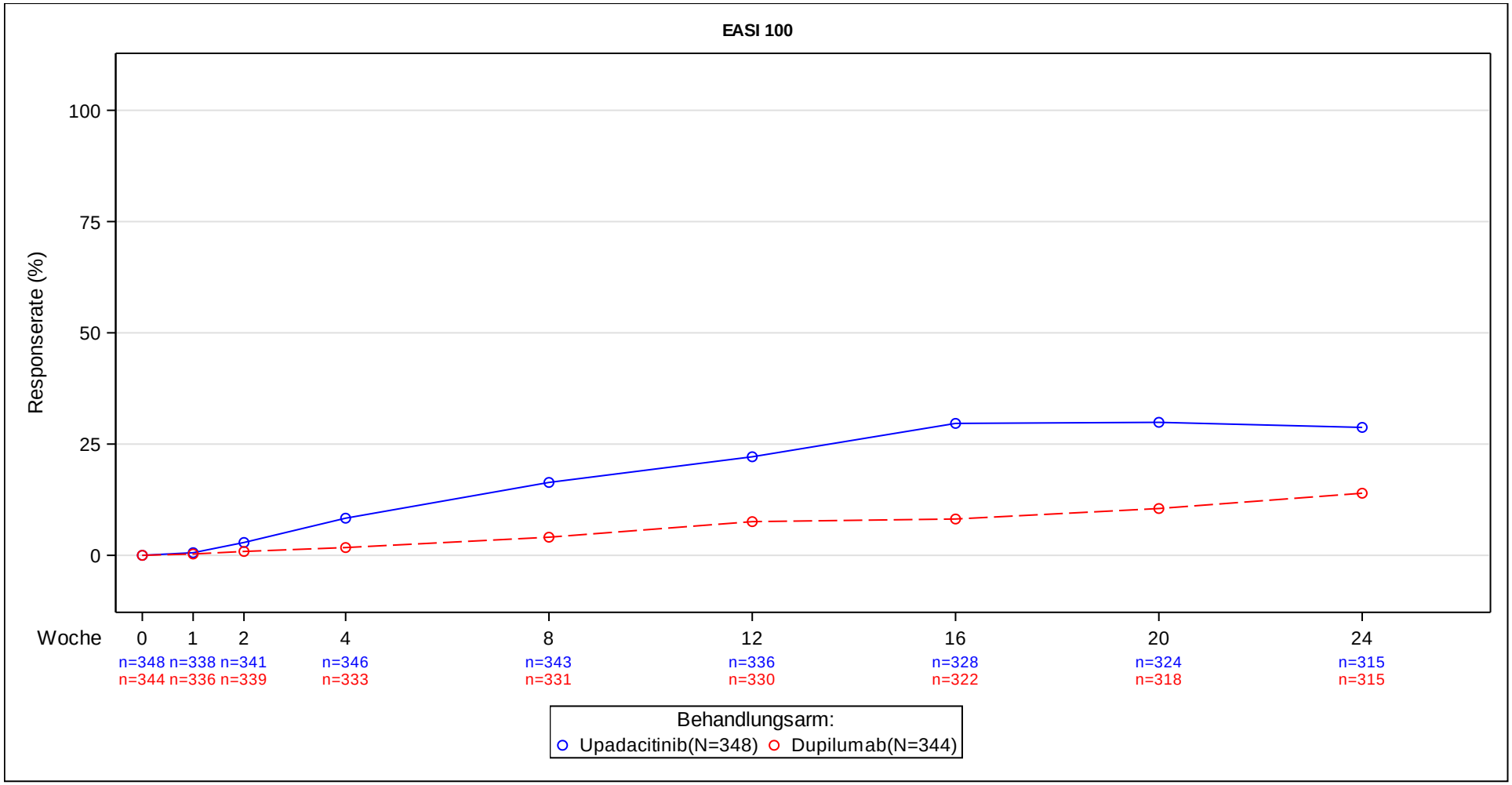
N=Number of patients, n=Number of patients with non-missing values, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.

Figure 2.4.2
Eczema Area and Severity Index (EASI) 90 response
(ITT Population)



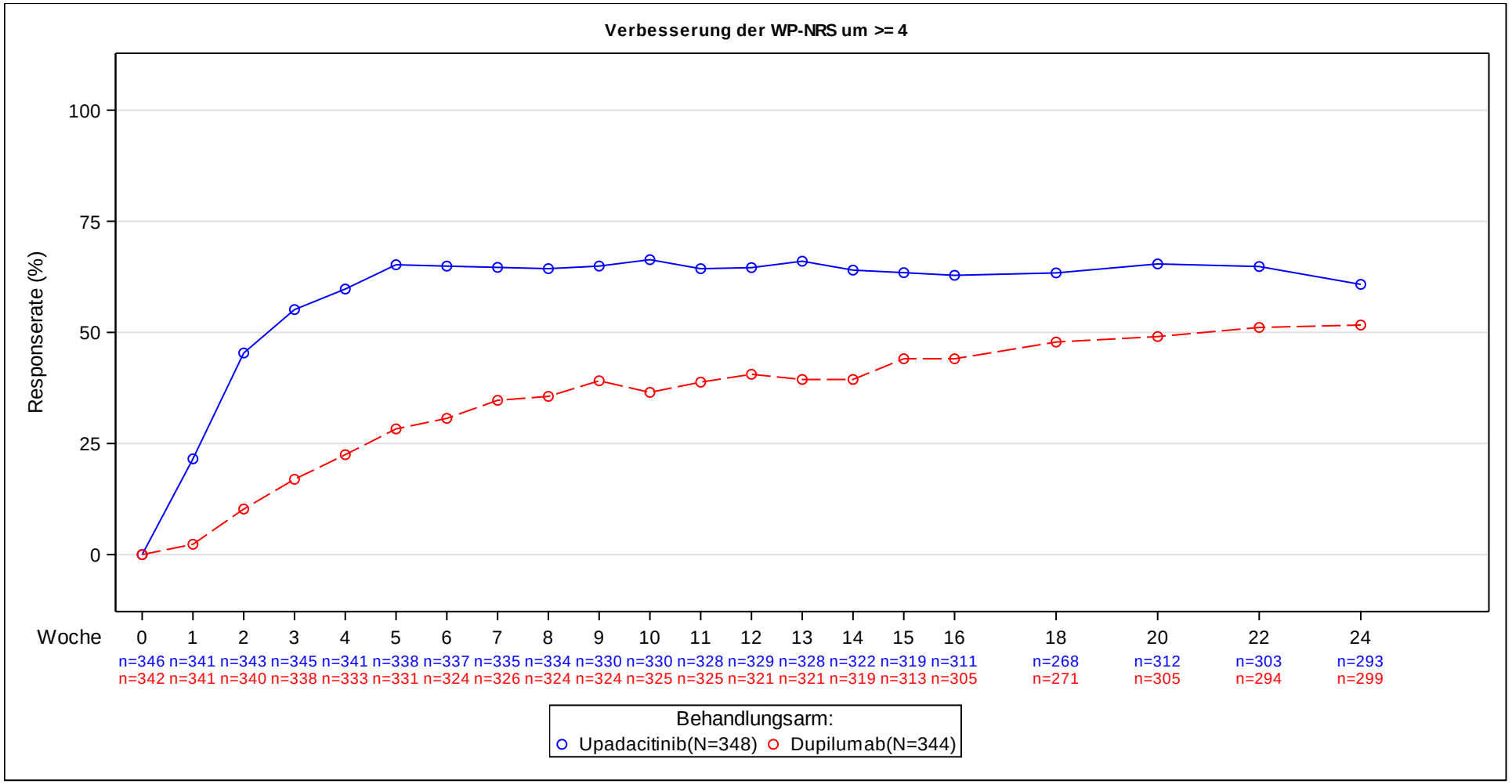
N=Number of patients, n=Number of patients with non-missing values, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.

Figure 2.4.3
Eczema Area and Severity Index (EASI) 100 response
(ITT Population)



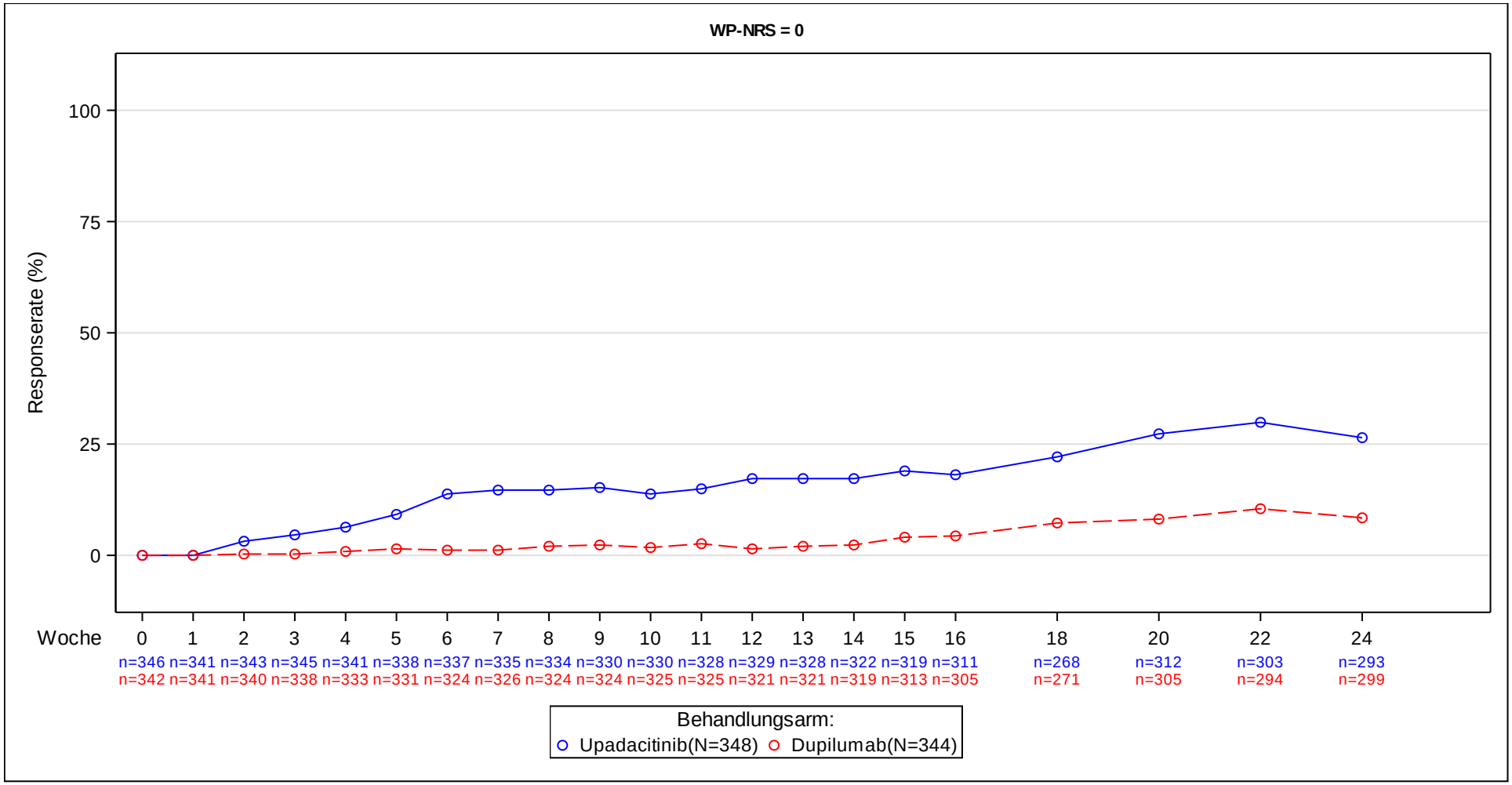
N=Number of patients, n=Number of patients with non-missing values, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.

Figure 2.4.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4
(ITT Population)

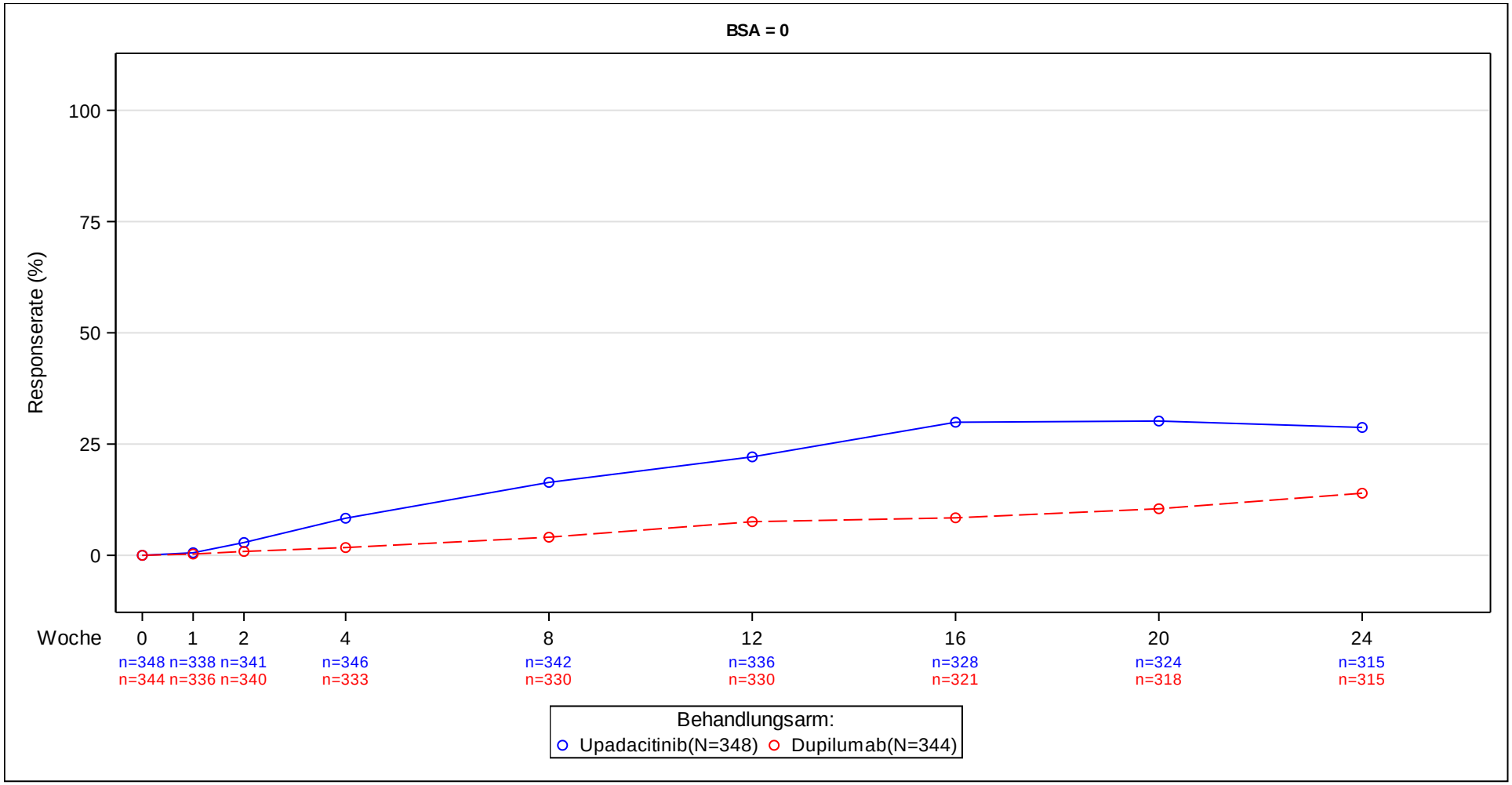


N=Number of patients, n=Number of patients with non-missing values, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.

Figure 2.4.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0
(ITT Population)

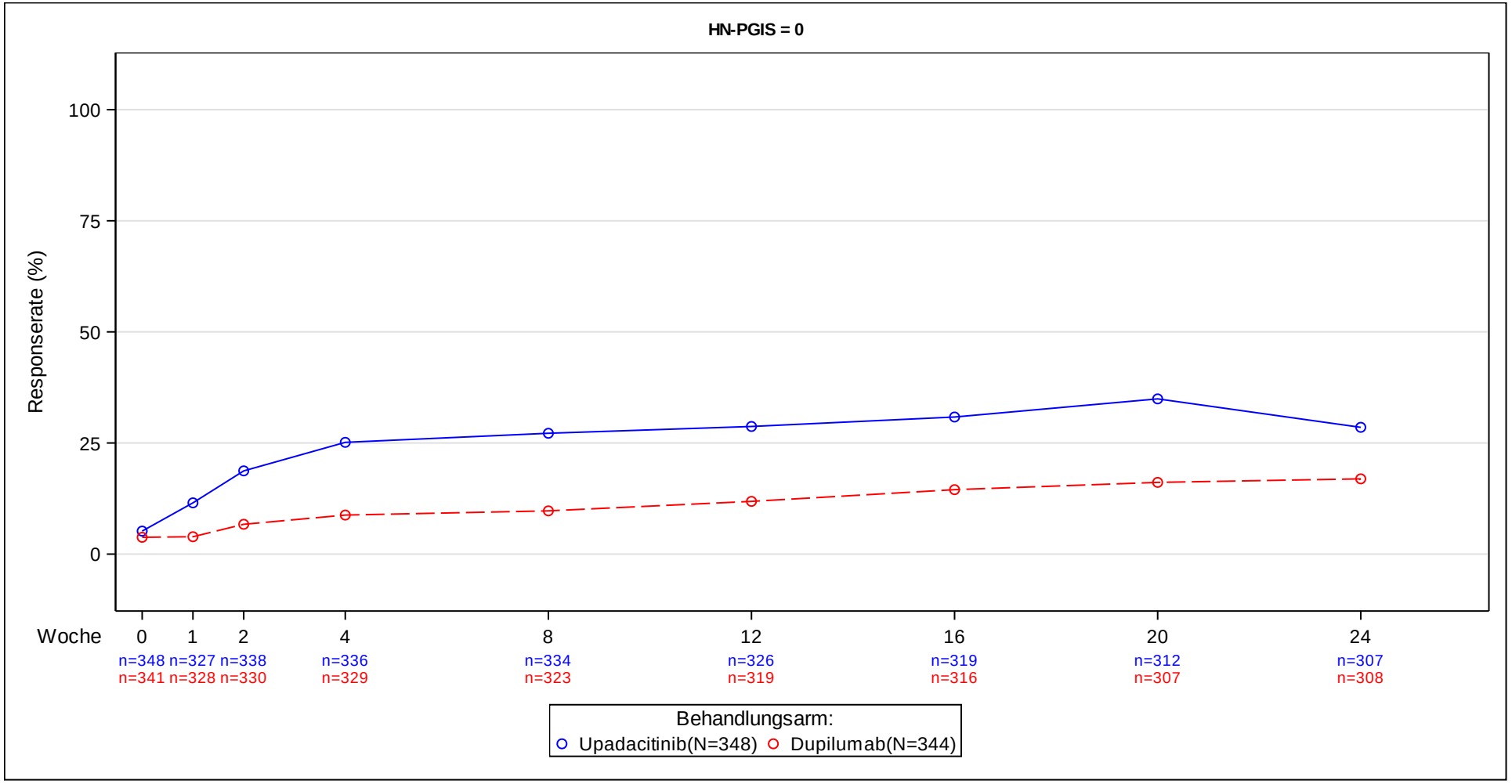


N=Number of patients, n=Number of patients with non-missing values, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.



N=Number of patients, n=Number of patients with non-missing values, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.

Figure 2.4.7
Head and Neck - Patient Global Impression of Severity (HN-PGIS) = 0
(ITT Population)



N=Number of patients, n=Number of patients with non-missing values, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.

Table 2.5.1
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 75 response (NRI/MI)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	57 (16.4)	20 (5.9)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	23 (6.6)	25 (7.3)
Week 2	Number of subjects with Response, n (%)	154 (44.1)	63 (18.2)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (2.9)	8 (2.3)
Week 4	Number of subjects with Response, n (%)	246 (70.8)	129 (37.6)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	9 (2.6)	13 (3.8)
Week 8	Number of subjects with Response, n (%)	289 (83.0)	208 (60.5)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (2.9)	19 (5.5)
Week 12	Number of subjects with Response, n (%)	295 (84.8)	234 (67.9)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	18 (5.2)	19 (5.5)
Week 16	Number of subjects with Response, n (%)	300 (86.3)	267 (77.7)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	26 (7.5)	25 (7.3)
Week 20	Number of subjects with Response, n (%)	298 (85.7)	274 (79.6)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	26 (7.5)	32 (9.3)
Week 24	Number of subjects with Response, n (%)	297 (85.3)	281 (81.8)
	Number of imputations (NRI), n (%)	3 (0.9)	1 (0.3)
	Number of imputations (MI), n (%)	33 (9.5)	30 (8.7)
	Adjusted Analysis		
	Odds Ratio	1.290	
	95% CI	0.841, 1.980	
	p-value	0.2432	
	Relative Risk	1.043	
	95% CI	0.972, 1.120	
	p-value	0.2390	
	Risk Difference	0.035	
	95% CI	-0.023, 0.094	
	p-value	0.2386	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values(missing data due to COVID-19 infection or logistical restriction and all other missing data) will be imputed by MI. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.5.2
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 90 response (NRI/MI)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	19 (5.3)	7 (2.1)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	23 (6.6)	25 (7.3)
Week 2	Number of subjects with Response, n (%)	65 (18.6)	21 (6.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (2.9)	8 (2.3)
Week 4	Number of subjects with Response, n (%)	151 (43.5)	52 (15.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	9 (2.6)	13 (3.8)
Week 8	Number of subjects with Response, n (%)	216 (62.0)	102 (29.8)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (2.9)	19 (5.5)
Week 12	Number of subjects with Response, n (%)	232 (66.7)	143 (41.4)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	18 (5.2)	19 (5.5)
Week 16	Number of subjects with Response, n (%)	241 (69.3)	158 (45.9)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	26 (7.5)	25 (7.3)
Week 20	Number of subjects with Response, n (%)	240 (68.9)	174 (50.7)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	26 (7.5)	32 (9.3)
Week 24	Number of subjects with Response, n (%)	234 (67.4)	204 (59.4)
	Number of imputations (NRI), n (%)	3 (0.9)	1 (0.3)
	Number of imputations (MI), n (%)	33 (9.5)	30 (8.7)
	Adjusted Analysis		
	Odds Ratio	1.412	
	95% CI	1.021, 1.953	
	p-value	0.0371	
	Relative Risk	1.130	
	95% CI	1.003, 1.273	
	p-value	0.0437	
	Risk Difference	0.079	
	95% CI	0.004, 0.153	
	p-value	0.0386	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values(missing data due to COVID-19 infection or logistical restriction and all other missing data) will be imputed by MI. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.5.3
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 100 response (NRI/MI)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	2 (0.6)	1 (0.3)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	23 (6.6)	25 (7.3)
Week 2	Number of subjects with Response, n (%)	10 (2.9)	3 (0.9)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (2.9)	8 (2.3)
Week 4	Number of subjects with Response, n (%)	29 (8.3)	6 (1.7)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	9 (2.6)	13 (3.8)
Week 8	Number of subjects with Response, n (%)	57 (16.4)	14 (4.1)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (2.9)	19 (5.5)
Week 12	Number of subjects with Response, n (%)	77 (22.2)	26 (7.6)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	18 (5.2)	19 (5.5)
Week 16	Number of subjects with Response, n (%)	103 (29.7)	28 (8.2)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	26 (7.5)	25 (7.3)
Week 20	Number of subjects with Response, n (%)	104 (29.9)	36 (10.6)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	26 (7.5)	32 (9.3)
Week 24	Number of subjects with Response, n (%)	100 (28.8)	48 (14.1)
	Number of imputations (NRI), n (%)	3 (0.9)	1 (0.3)
	Number of imputations (MI), n (%)	33 (9.5)	30 (8.7)
	Adjusted Analysis		
	Odds Ratio	2.486	
	95% CI	1.691, 3.656	
	p-value	<.0001	
	Relative Risk	2.033	
	95% CI	1.493, 2.767	
	p-value	<.0001	
	Risk Difference	0.145	
	95% CI	0.086, 0.205	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values(missing data due to COVID-19 infection or logistical restriction and all other missing data) will be imputed by MI. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.5.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	76 (21.9)	8 (2.4)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	7 (2.0)	4 (1.2)
Week 2	Number of subjects with Response, n (%)	158 (45.4)	36 (10.5)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	6 (1.7)	5 (1.5)
Week 3	Number of subjects with Response, n (%)	192 (55.3)	59 (17.2)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	4 (1.1)	7 (2.0)
Week 4	Number of subjects with Response, n (%)	210 (60.4)	79 (22.9)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	8 (2.3)	12 (3.5)
Week 5	Number of subjects with Response, n (%)	230 (66.2)	100 (29.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	11 (3.2)	14 (4.1)
Week 6	Number of subjects with Response, n (%)	231 (66.4)	109 (31.6)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	12 (3.4)	21 (6.1)
Week 7	Number of subjects with Response, n (%)	231 (66.3)	123 (35.9)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	14 (4.0)	19 (5.5)
Week 8	Number of subjects with Response, n (%)	231 (66.3)	127 (36.8)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	15 (4.3)	21 (6.1)
Week 9	Number of subjects with Response, n (%)	236 (67.8)	141 (40.8)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	19 (5.5)	21 (6.1)
Week 10	Number of subjects with Response, n (%)	242 (69.5)	131 (38.1)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	20 (5.7)	20 (5.8)
Week 11	Number of subjects with Response, n (%)	236 (67.9)	138 (40.2)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	21 (6.0)	20 (5.8)
Week 12	Number of subjects with Response, n (%)	237 (68.1)	147 (42.6)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	20 (5.7)	24 (7.0)
Week 13	Number of subjects with Response, n (%)	242 (69.5)	143 (41.6)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	21 (6.0)	24 (7.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values(missing data due to COVID-19 infection or logistical restriction and all other missing data) will be imputed by MI. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.5.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 14	Number of subjects with Response, n (%)	237 (68.1)	143 (41.6)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	27 (7.8)	25 (7.3)
Week 15	Number of subjects with Response, n (%)	238 (68.5)	161 (46.7)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	30 (8.6)	31 (9.0)
Week 16	Number of subjects with Response, n (%)	237 (68.2)	161 (46.8)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	38 (10.9)	39 (11.3)
Week 18	Number of subjects with Response, n (%)	242 (69.4)	181 (52.6)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	85 (24.4)	77 (22.4)
Week 20	Number of subjects with Response, n (%)	244 (70.0)	182 (52.8)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	37 (10.6)	42 (12.2)
Week 22	Number of subjects with Response, n (%)	244 (70.1)	190 (55.3)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	48 (13.8)	53 (15.4)
Week 24	Number of subjects with Response, n (%)	239 (68.7)	200 (58.2)
	Number of imputations (NRI), n (%)	3 (0.9)	1 (0.3)
	Number of imputations (MI), n (%)	54 (15.5)	45 (13.1)
	Adjusted Analysis		
	Odds Ratio	1.582	
	95% CI	1.149, 2.178	
	p-value	0.0050	
	Relative Risk	1.180	
	95% CI	1.051, 1.326	
	p-value	0.0052	
	Risk Difference	0.105	
	95% CI	0.033, 0.178	
	p-value	0.0046	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values(missing data due to COVID-19 infection or logistical restriction and all other missing data) will be imputed by MI. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.5.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	7 (2.0)	4 (1.2)
Week 2	Number of subjects with Response, n (%)	11 (3.2)	1 (0.3)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	6 (1.7)	5 (1.5)
Week 3	Number of subjects with Response, n (%)	16 (4.6)	1 (0.3)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	4 (1.1)	7 (2.0)
Week 4	Number of subjects with Response, n (%)	22 (6.3)	3 (0.9)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	8 (2.3)	12 (3.5)
Week 5	Number of subjects with Response, n (%)	32 (9.2)	5 (1.5)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	11 (3.2)	14 (4.1)
Week 6	Number of subjects with Response, n (%)	48 (13.8)	4 (1.2)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	12 (3.4)	21 (6.1)
Week 7	Number of subjects with Response, n (%)	51 (14.7)	4 (1.2)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	14 (4.0)	19 (5.5)
Week 8	Number of subjects with Response, n (%)	51 (14.7)	7 (2.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	15 (4.3)	21 (6.1)
Week 9	Number of subjects with Response, n (%)	53 (15.2)	8 (2.3)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	19 (5.5)	21 (6.1)
Week 10	Number of subjects with Response, n (%)	48 (13.8)	6 (1.7)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	20 (5.7)	20 (5.8)
Week 11	Number of subjects with Response, n (%)	52 (14.9)	9 (2.6)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	21 (6.0)	20 (5.8)
Week 12	Number of subjects with Response, n (%)	60 (17.2)	5 (1.5)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	20 (5.7)	24 (7.0)
Week 13	Number of subjects with Response, n (%)	60 (17.2)	7 (2.0)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	21 (6.0)	24 (7.0)
Week 14	Number of subjects with Response, n (%)	60 (17.2)	8 (2.3)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	27 (7.8)	25 (7.3)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values(missing data due to COVID-19 infection or logistical restriction and all other missing data) will be imputed by MI. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.5.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 15	Number of subjects with Response, n (%)	66 (19.0)	14 (4.1)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	30 (8.6)	31 (9.0)
Week 16	Number of subjects with Response, n (%)	62 (17.8)	15 (4.4)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	38 (10.9)	39 (11.3)
Week 18	Number of subjects with Response, n (%)	71 (20.4)	23 (6.7)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	85 (24.4)	77 (22.4)
Week 20	Number of subjects with Response, n (%)	95 (27.3)	27 (7.8)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	37 (10.6)	42 (12.2)
Week 22	Number of subjects with Response, n (%)	102 (29.3)	36 (10.5)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	48 (13.8)	53 (15.4)
Week 24	Number of subjects with Response, n (%)	92 (26.4)	29 (8.4)
	Number of imputations (NRI), n (%)	3 (0.9)	1 (0.3)
	Number of imputations (MI), n (%)	54 (15.5)	45 (13.1)
	Adjusted Analysis		
	Odds Ratio	3.905	
	95% CI	2.493, 6.117	
	p-value	<.0001	
	Relative Risk	3.135	
	95% CI	2.123, 4.630	
	p-value	<.0001	
	Risk Difference	0.180	
	95% CI	0.126, 0.235	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values(missing data due to COVID-19 infection or logistical restriction and all other missing data) will be imputed by MI. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.5.6
Sensitivity Analysis of Body Surface Area (BSA) = 0 (NRI/MI)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	2 (0.6)	1 (0.3)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	23 (6.6)	25 (7.3)
Week 2	Number of subjects with Response, n (%)	10 (2.9)	3 (0.9)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (2.9)	7 (2.0)
Week 4	Number of subjects with Response, n (%)	29 (8.3)	6 (1.7)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	9 (2.6)	13 (3.8)
Week 8	Number of subjects with Response, n (%)	57 (16.4)	14 (4.1)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	11 (3.2)	20 (5.8)
Week 12	Number of subjects with Response, n (%)	77 (22.1)	26 (7.6)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	17 (4.9)	19 (5.5)
Week 16	Number of subjects with Response, n (%)	104 (29.9)	29 (8.4)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	26 (7.5)	26 (7.6)
Week 20	Number of subjects with Response, n (%)	105 (30.2)	36 (10.5)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	26 (7.5)	32 (9.3)
Week 24	Number of subjects with Response, n (%)	100 (28.8)	48 (14.0)
	Number of imputations (NRI), n (%)	3 (0.9)	1 (0.3)
	Number of imputations (MI), n (%)	33 (9.5)	30 (8.7)
	Adjusted Analysis		
	Odds Ratio	2.502	
	95% CI	1.702, 3.679	
	p-value	<.0001	
	Relative Risk	2.045	
	95% CI	1.502, 2.785	
	p-value	<.0001	
	Risk Difference	0.146	
	95% CI	0.087, 0.205	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values(missing data due to COVID-19 infection or logistical restriction and all other missing data) will be imputed by MI. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 2.5.7
Sensitivity Analysis of Head and Neck - Patient Global Impression of Severity (HN-PGIS) = 0 (NRI/MI)
(ITT Population)

Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 1	Number of subjects with Response, n (%)	41 (11.9)	13 (3.8)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	33 (9.5)	29 (8.4)
Week 2	Number of subjects with Response, n (%)	67 (19.1)	23 (6.7)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	13 (3.7)	17 (4.9)
Week 4	Number of subjects with Response, n (%)	88 (25.4)	31 (8.9)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	18 (5.2)	19 (5.5)
Week 8	Number of subjects with Response, n (%)	95 (27.4)	35 (10.2)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	21 (6.0)	30 (8.7)
Week 12	Number of subjects with Response, n (%)	103 (29.6)	42 (12.1)
	Number of imputations (NRI), n (%)	1 (0.3)	0 (0.0)
	Number of imputations (MI), n (%)	28 (8.0)	32 (9.3)
Week 16	Number of subjects with Response, n (%)	111 (32.0)	52 (15.2)
	Number of imputations (NRI), n (%)	0 (0.0)	1 (0.3)
	Number of imputations (MI), n (%)	35 (10.1)	31 (9.0)
Week 20	Number of subjects with Response, n (%)	126 (36.2)	61 (17.6)
	Number of imputations (NRI), n (%)	1 (0.3)	1 (0.3)
	Number of imputations (MI), n (%)	37 (10.6)	41 (11.9)
Week 24	Number of subjects with Response, n (%)	105 (30.1)	62 (18.0)
	Number of imputations (NRI), n (%)	3 (0.9)	1 (0.3)
	Number of imputations (MI), n (%)	40 (11.5)	37 (10.8)
	Adjusted Analysis		
	Odds Ratio	1.967	
	95% CI	1.353, 2.859	
	p-value	0.0004	
	Relative Risk	1.681	
	95% CI	1.260, 2.243	
	p-value	0.0004	
	Risk Difference	0.119	
	95% CI	0.053, 0.184	
	p-value	0.0004	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values(missing data due to COVID-19 infection or logistical restriction and all other missing data) will be imputed by MI. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.

Table 3.1.1
Adverse Events
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	271 (77.9)	230 (66.9)
Unstratified Analysis		
Odds Ratio	1.744	
95% CI	1.244, 2.447	
p-value	0.0013	
Relative Risk	1.165	
95% CI	1.061, 1.278	
p-value	0.0013	
Risk Difference	0.110	
95% CI	0.044, 0.176	
p-value	0.0011	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.1.1
Adverse Events - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.9804
< 40 years	182/228 (79.8)	155/226 (68.6)	1.164	(1.043, 1.299)	0.0067	
>= 40 years	89/120 (74.2)	75/118 (63.6)	1.167	(0.982, 1.387)	0.0798	
Geographic regions						0.9534
US/PR/Canada	93/140 (66.4)	74/131 (56.5)	1.176	(0.972, 1.423)	0.0961	
Other	178/208 (85.6)	156/213 (73.2)	1.168	(1.059, 1.289)	0.0019	
Baseline EASI						0.0381
< Median (26.4)	125/165 (75.8)	106/180 (58.9)	1.286	(1.108, 1.494)	0.0010	
>= Median (26.4)	146/183 (79.8)	124/164 (75.6)	1.055	(0.942, 1.182)	0.3536	
Baseline vIGA-AD						0.5881
3 (Moderate)	128/174 (73.6)	105/171 (61.4)	1.198	(1.033, 1.390)	0.0171	
4 (Severe)	143/174 (82.2)	125/173 (72.3)	1.137	(1.013, 1.277)	0.0287	
Sex						0.1247
Female	123/165 (74.5)	104/150 (69.3)	1.075	(0.936, 1.235)	0.3062	
Male	148/183 (80.9)	126/194 (64.9)	1.245	(1.099, 1.411)	0.0006	
BMI						0.5953
< 25 kg/m2	127/161 (78.9)	116/169 (68.6)	1.149	(1.010, 1.308)	0.0353	
>= 25 - < 30 kg/m2	69/ 93 (74.2)	71/110 (64.5)	1.149	(0.957, 1.381)	0.1361	
>= 30 kg/m2	75/ 93 (80.6)	43/ 65 (66.2)	1.219	(0.998, 1.490)	0.0527	
Race						0.9157
White	177/235 (75.3)	161/244 (66.0)	1.141	(1.016, 1.282)	0.0255	
Asian	64/ 77 (83.1)	53/ 78 (67.9)	1.223	(1.019, 1.468)	0.0306	
Other	30/ 36 (83.3)	16/ 22 (72.7)	1.146	(0.853, 1.538)	0.3652	
Baseline hsCRP						0.5729
< Median (1.745)	127/161 (78.9)	122/185 (65.9)	1.196	(1.049, 1.363)	0.0073	
>= Median(1.745)	144/187 (77.0)	108/159 (67.9)	1.134	(0.993, 1.294)	0.0633	
Previous systemic therapy						0.1750
With	149/180 (82.8)	132/175 (75.4)	1.097	(0.985, 1.222)	0.0905	
Without	122/168 (72.6)	98/169 (58.0)	1.252	(1.069, 1.467)	0.0054	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.2
Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 24	Number of subjects with events, n (%)	269 (77.3)	227 (66.0)
	Unstratified Analysis		
	Odds Ratio	1.755	
	95% CI	1.255, 2.455	
	p-value	0.0010	
	Relative Risk	1.171	
	95% CI	1.065, 1.288	
	p-value	0.0011	
	Risk Difference	0.113	
	95% CI	0.046, 0.180	
	p-value	0.0009	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.3
Serious Adverse Events
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	14 (4.0)	7 (2.0)
Unstratified Analysis		
Odds Ratio	2.018	
95% CI	0.804, 5.063	
p-value	0.1346	
Relative Risk	1.977	
95% CI	0.808, 4.838	
p-value	0.1355	
Risk Difference	0.020	
95% CI	-0.006, 0.045	
p-value	0.1261	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.3.1
Serious Adverse Events - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.9931
< 40 years	8/228 (3.5)	4/226 (1.8)	1.982	(0.605, 6.491)	0.2581	
>= 40 years	6/120 (5.0)	3/118 (2.5)	1.967	(0.504, 7.681)	0.3306	
Geographic regions						0.1954
US/PR/Canada	6/140 (4.3)	1/131 (0.8)	5.614	(0.685, 46.010)	0.1079	
Other	8/208 (3.8)	6/213 (2.8)	1.365	(0.482, 3.867)	0.5577	
Baseline EASI						0.9118
< Median (26.4)	5/165 (3.0)	3/180 (1.7)	1.818	(0.441, 7.490)	0.4078	
>= Median (26.4)	9/183 (4.9)	4/164 (2.4)	2.016	(0.633, 6.424)	0.2355	
Baseline vIGA-AD						0.7635
3 (Moderate)	7/174 (4.0)	3/171 (1.8)	2.293	(0.603, 8.722)	0.2234	
4 (Severe)	7/174 (4.0)	4/173 (2.3)	1.740	(0.519, 5.837)	0.3698	
Sex						0.1565
Female	9/165 (5.5)	2/150 (1.3)	4.091	(0.898, 18.632)	0.0686	
Male	5/183 (2.7)	5/194 (2.6)	1.060	(0.312, 3.602)	0.9255	
BMI						0.3478
< 25 kg/m2	6/161 (3.7)	2/169 (1.2)	3.149	(0.645, 15.376)	0.1562	
>= 25 - < 30 kg/m2	3/ 93 (3.2)	2/110 (1.8)	1.774	(0.303, 10.393)	0.5250	
>= 30 kg/m2	5/ 93 (5.4)	3/ 65 (4.6)	1.165	(0.288, 4.704)	0.8303	
Race						0.1890
White	8/235 (3.4)	6/244 (2.5)	1.384	(0.488, 3.929)	0.5411	
Asian	4/ 77 (5.2)	1/ 78 (1.3)	4.052	(0.463, 35.437)	0.2060	
Other	2/ 36 (5.6)	0/ 22 (0.0)	3.108	(0.156, 61.895)	0.4575	
Baseline hsCRP						0.6095
< Median (1.745)	2/161 (1.2)	2/185 (1.1)	1.149	(0.164, 8.065)	0.8888	
>= Median(1.745)	12/187 (6.4)	5/159 (3.1)	2.041	(0.735, 5.668)	0.1712	
Previous systemic therapy						0.3189
With	7/180 (3.9)	5/175 (2.9)	1.361	(0.440, 4.208)	0.5924	
Without	7/168 (4.2)	2/169 (1.2)	3.521	(0.742, 16.703)	0.1131	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.4
Serious Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 24	Number of subjects with events, n (%)	13 (3.7)	7 (2.0)
	Unstratified Analysis		
	Odds Ratio	1.868	
	95% CI	0.736, 4.741	
	p-value	0.1884	
	Relative Risk	1.836	
	95% CI	0.741, 4.546	
	p-value	0.1891	
	Risk Difference	0.017	
	95% CI	-0.008, 0.042	
	p-value	0.1805	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.5
Adverse Events of CTCAE Grade >=3
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	31 (8.9)	15 (4.4)
Unstratified Analysis		
Odds Ratio	2.145	
95% CI	1.136, 4.049	
p-value	0.0186	
Relative Risk	2.043	
95% CI	1.123, 3.716	
p-value	0.0192	
Risk Difference	0.045	
95% CI	0.009, 0.082	
p-value	0.0157	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.5.1
Adverse Events of CTCAE Grade >=3 - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.7516
< 40 years	22/228 (9.6)	10/226 (4.4)	2.181	(1.057, 4.500)	0.0349	
>= 40 years	9/120 (7.5)	5/118 (4.2)	1.770	(0.611, 5.126)	0.2926	
Geographic regions						0.3633
US/PR/Canada	13/140 (9.3)	4/131 (3.1)	3.041	(1.017, 9.091)	0.0465	
Other	18/208 (8.7)	11/213 (5.2)	1.676	(0.811, 3.461)	0.1630	
Baseline EASI						0.3718
< Median (26.4)	13/165 (7.9)	5/180 (2.8)	2.836	(1.034, 7.784)	0.0430	
>= Median (26.4)	18/183 (9.8)	10/164 (6.1)	1.613	(0.767, 3.394)	0.2076	
Baseline vIGA-AD						0.9164
3 (Moderate)	12/174 (6.9)	6/171 (3.5)	1.966	(0.755, 5.118)	0.1664	
4 (Severe)	19/174 (10.9)	9/173 (5.2)	2.099	(0.977, 4.509)	0.0574	
Sex						0.0043
Female	18/165 (10.9)	2/150 (1.3)	8.182	(1.931, 34.673)	0.0043	
Male	13/183 (7.1)	13/194 (6.7)	1.060	(0.505, 2.226)	0.8774	
BMI						0.2846
< 25 kg/m2	15/161 (9.3)	10/169 (5.9)	1.575	(0.729, 3.402)	0.2482	
>= 25 - < 30 kg/m2	7/ 93 (7.5)	3/110 (2.7)	2.760	(0.734, 10.373)	0.1329	
>= 30 kg/m2	9/ 93 (9.7)	2/ 65 (3.1)	3.145	(0.702, 14.082)	0.1341	
Race						0.8070
White	19/235 (8.1)	9/244 (3.7)	2.192	(1.012, 4.746)	0.0465	
Asian	6/ 77 (7.8)	5/ 78 (6.4)	1.216	(0.387, 3.817)	0.7381	
Other	6/ 36 (16.7)	1/ 22 (4.5)	3.667	(0.472, 28.468)	0.2140	
Baseline hsCRP						0.4868
< Median (1.745)	11/161 (6.8)	8/185 (4.3)	1.580	(0.652, 3.832)	0.3115	
>= Median(1.745)	20/187 (10.7)	7/159 (4.4)	2.429	(1.055, 5.596)	0.0371	
Previous systemic therapy						0.8660
With	16/180 (8.9)	8/175 (4.6)	1.944	(0.854, 4.427)	0.1132	
Without	15/168 (8.9)	7/169 (4.1)	2.156	(0.902, 5.152)	0.0841	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.6
Adverse Events of CTCAE Grade >=3 (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=348)	Dupilumab (N=344)
Week 24	Number of subjects with events, n (%)	29 (8.3)	13 (3.8)
	Unstratified Analysis		
	Odds Ratio	2.315	
	95% CI	1.182, 4.533	
	p-value	0.0144	
	Relative Risk	2.205	
	95% CI	1.166, 4.169	
	p-value	0.0150	
	Risk Difference	0.046	
	95% CI	0.010, 0.081	
	p-value	0.0116	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.7
Adverse Events of CTCAE Grade <3
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	268 (77.0)	223 (64.8)
Unstratified Analysis		
Odds Ratio	1.818	
95% CI	1.302, 2.538	
p-value	0.0004	
Relative Risk	1.188	
95% CI	1.078, 1.309	
p-value	0.0005	
Risk Difference	0.122	
95% CI	0.055, 0.189	
p-value	0.0004	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.7.1
Adverse Events of CTCAE Grade <3 - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.9998
< 40 years	181/228 (79.4)	151/226 (66.8)	1.188	(1.061, 1.331)	0.0028	
>= 40 years	87/120 (72.5)	72/118 (61.0)	1.188	(0.991, 1.425)	0.0626	
Geographic regions						0.8175
US/PR/Canada	91/140 (65.0)	70/131 (53.4)	1.216	(0.995, 1.487)	0.0559	
Other	177/208 (85.1)	153/213 (71.8)	1.185	(1.070, 1.311)	0.0011	
Baseline EASI						0.0666
< Median (26.4)	124/165 (75.2)	104/180 (57.8)	1.301	(1.117, 1.515)	0.0007	
>= Median (26.4)	144/183 (78.7)	119/164 (72.6)	1.084	(0.961, 1.223)	0.1876	
Baseline vIGA-AD						0.5829
3 (Moderate)	127/174 (73.0)	102/171 (59.6)	1.224	(1.050, 1.426)	0.0097	
4 (Severe)	141/174 (81.0)	121/173 (69.9)	1.159	(1.026, 1.308)	0.0174	
Sex						0.0337
Female	120/165 (72.7)	103/150 (68.7)	1.059	(0.918, 1.222)	0.4307	
Male	148/183 (80.9)	120/194 (61.9)	1.307	(1.147, 1.491)	<.0001	
BMI						0.8777
< 25 kg/m2	126/161 (78.3)	112/169 (66.3)	1.181	(1.032, 1.351)	0.0157	
>= 25 - < 30 kg/m2	69/ 93 (74.2)	68/110 (61.8)	1.200	(0.993, 1.451)	0.0592	
>= 30 kg/m2	73/ 93 (78.5)	43/ 65 (66.2)	1.187	(0.968, 1.455)	0.1001	
Race						0.9722
White	175/235 (74.5)	157/244 (64.3)	1.157	(1.027, 1.305)	0.0167	
Asian	64/ 77 (83.1)	50/ 78 (64.1)	1.297	(1.068, 1.575)	0.0087	
Other	29/ 36 (80.6)	16/ 22 (72.7)	1.108	(0.819, 1.498)	0.5071	
Baseline hsCRP						0.3216
< Median (1.745)	127/161 (78.9)	117/185 (63.2)	1.247	(1.089, 1.429)	0.0014	
>= Median(1.745)	141/187 (75.4)	106/159 (66.7)	1.131	(0.986, 1.297)	0.0783	
Previous systemic therapy						0.0850
With	147/180 (81.7)	130/175 (74.3)	1.099	(0.984, 1.229)	0.0953	
Without	121/168 (72.0)	93/169 (55.0)	1.309	(1.109, 1.545)	0.0015	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.8
Adverse Events leading to discontinuation of study drug
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	11 (3.2)	4 (1.2)
Unstratified Analysis		
Odds Ratio	2.774	
95% CI	0.875, 8.800	
p-value	0.0831	
Relative Risk	2.718	
95% CI	0.874, 8.454	
p-value	0.0841	
Risk Difference	0.020	
95% CI	-0.002, 0.042	
p-value	0.0697	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.8.1
Adverse Events leading to discontinuation of study drug - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.0465
< 40 years	6/228 (2.6)	4/226 (1.8)	1.487	(0.425, 5.198)	0.5345	
>= 40 years	5/120 (4.2)	0/118 (0.0)	10.818	(0.605, 193.486)	0.1056	
Geographic regions						0.3332
US/PR/Canada	6/140 (4.3)	1/131 (0.8)	5.614	(0.685, 46.010)	0.1079	
Other	5/208 (2.4)	3/213 (1.4)	1.707	(0.413, 7.051)	0.4601	
Baseline EASI						0.8108
< Median (26.4)	3/165 (1.8)	1/180 (0.6)	3.273	(0.344, 31.153)	0.3024	
>= Median (26.4)	8/183 (4.4)	3/164 (1.8)	2.390	(0.645, 8.858)	0.1924	
Baseline vIGA-AD						0.4675
3 (Moderate)	5/174 (2.9)	1/171 (0.6)	4.914	(0.580, 41.624)	0.1442	
4 (Severe)	6/174 (3.4)	3/173 (1.7)	1.989	(0.505, 7.824)	0.3254	
Sex						0.3876
Female	6/165 (3.6)	3/150 (2.0)	1.818	(0.463, 7.142)	0.3918	
Male	5/183 (2.7)	1/194 (0.5)	5.301	(0.625, 44.940)	0.1262	
BMI						0.4099
< 25 kg/m2	5/161 (3.1)	1/169 (0.6)	5.248	(0.620, 44.438)	0.1282	
>= 25 - < 30 kg/m2	4/ 93 (4.3)	2/110 (1.8)	2.366	(0.443, 12.627)	0.3136	
>= 30 kg/m2	2/ 93 (2.2)	1/ 65 (1.5)	1.398	(0.129, 15.095)	0.7826	
Race						NE
White	6/235 (2.6)	4/244 (1.6)	1.557	(0.445, 5.449)	0.4881	
Asian	3/ 77 (3.9)	0/ 78 (0.0)	7.090	(0.372, 135.000)	0.1926	
Other	2/ 36 (5.6)	0/ 22 (0.0)	3.108	(0.156, 61.895)	0.4575	
Baseline hsCRP						0.3235
< Median (1.745)	5/161 (3.1)	1/185 (0.5)	5.745	(0.678, 48.667)	0.1088	
>= Median(1.745)	6/187 (3.2)	3/159 (1.9)	1.701	(0.432, 6.690)	0.4474	
Previous systemic therapy						0.2837
With	5/180 (2.8)	3/175 (1.7)	1.620	(0.393, 6.678)	0.5041	
Without	6/168 (3.6)	1/169 (0.6)	6.036	(0.735, 49.596)	0.0944	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.9
Fatal Adverse Events
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.9.1
Fatal Adverse Events - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	1/120 (0.8)	0/118 (0.0)	2.950	(0.121, 71.703)	0.5063	
Geographic regions						NE
US/PR/Canada	1/140 (0.7)	0/131 (0.0)	2.809	(0.115, 68.337)	0.5260	
Other	0/208 (0.0)	0/213 (0.0)	NE	(NE, NE)	NE	
Baseline EASI						NE
< Median (26.4)	0/165 (0.0)	0/180 (0.0)	NE	(NE, NE)	NE	
>= Median (26.4)	1/183 (0.5)	0/164 (0.0)	2.690	(0.110, 65.583)	0.5436	
Baseline vIGA-AD						NE
3 (Moderate)	0/174 (0.0)	0/171 (0.0)	NE	(NE, NE)	NE	
4 (Severe)	1/174 (0.6)	0/173 (0.0)	2.983	(0.122, 72.719)	0.5024	
Sex						NE
Female	1/165 (0.6)	0/150 (0.0)	2.729	(0.112, 66.481)	0.5377	
Male	0/183 (0.0)	0/194 (0.0)	NE	(NE, NE)	NE	
BMI						NE
< 25 kg/m2	0/161 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	
>= 25 - < 30 kg/m2	0/ 93 (0.0)	0/110 (0.0)	NE	(NE, NE)	NE	
>= 30 kg/m2	1/ 93 (1.1)	0/ 65 (0.0)	2.106	(0.087, 50.910)	0.6466	
Race						NE
White	0/235 (0.0)	0/244 (0.0)	NE	(NE, NE)	NE	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	1/ 36 (2.8)	0/ 22 (0.0)	1.865	(0.079, 43.869)	0.6989	
Baseline hsCRP						NE
< Median (1.745)	0/161 (0.0)	0/185 (0.0)	NE	(NE, NE)	NE	
>= Median(1.745)	1/187 (0.5)	0/159 (0.0)	2.553	(0.105, 62.240)	0.5651	
Previous systemic therapy						NE
With	0/180 (0.0)	0/175 (0.0)	NE	(NE, NE)	NE	
Without	1/168 (0.6)	0/169 (0.0)	3.018	(0.124, 73.555)	0.4979	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.1
Adverse Events of Special Interest - Serious Infection
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	4 (1.1)	2 (0.6)
Unstratified Analysis		
Odds Ratio	1.988	
95% CI	0.362, 10.927	
p-value	0.4292	
Relative Risk	1.977	
95% CI	0.364, 10.723	
p-value	0.4295	
Risk Difference	0.006	
95% CI	-0.008, 0.019	
p-value	0.4192	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.1.1
Adverse Events of Special Interest - Serious Infection - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.3385
< 40 years	1/228 (0.4)	0/226 (0.0)	2.974	(0.122, 72.616)	0.5038	
>= 40 years	3/120 (2.5)	2/118 (1.7)	1.475	(0.251, 8.669)	0.6671	
Geographic regions						0.0556
US/PR/Canada	3/140 (2.1)	0/131 (0.0)	6.553	(0.342, 125.665)	0.2122	
Other	1/208 (0.5)	2/213 (0.9)	0.512	(0.047, 5.604)	0.5835	
Baseline EASI						0.9093
< Median (26.4)	2/165 (1.2)	1/180 (0.6)	2.182	(0.200, 23.838)	0.5225	
>= Median (26.4)	2/183 (1.1)	1/164 (0.6)	1.792	(0.164, 19.584)	0.6324	
Baseline vIGA-AD						0.1485
3 (Moderate)	2/174 (1.1)	0/171 (0.0)	4.914	(0.238, 101.617)	0.3029	
4 (Severe)	2/174 (1.1)	2/173 (1.2)	0.994	(0.142, 6.979)	0.9954	
Sex						0.1676
Female	2/165 (1.2)	0/150 (0.0)	4.548	(0.220, 93.980)	0.3269	
Male	2/183 (1.1)	2/194 (1.0)	1.060	(0.151, 7.448)	0.9532	
BMI						NE
< 25 kg/m2	0/161 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	
>= 25 - < 30 kg/m2	2/ 93 (2.2)	0/110 (0.0)	5.904	(0.287, 121.460)	0.2498	
>= 30 kg/m2	2/ 93 (2.2)	2/ 65 (3.1)	0.699	(0.101, 4.835)	0.7166	
Race						NE
White	1/235 (0.4)	2/244 (0.8)	0.519	(0.047, 5.687)	0.5914	
Asian	1/ 77 (1.3)	0/ 78 (0.0)	3.038	(0.126, 73.452)	0.4941	
Other	2/ 36 (5.6)	0/ 22 (0.0)	3.108	(0.156, 61.895)	0.4575	
Baseline hsCRP						1.0000
< Median (1.745)	0/161 (0.0)	0/185 (0.0)	NE	(NE, NE)	NE	
>= Median(1.745)	4/187 (2.1)	2/159 (1.3)	1.701	(0.316, 9.162)	0.5366	
Previous systemic therapy						0.0480
With	1/180 (0.6)	2/175 (1.1)	0.486	(0.044, 5.313)	0.5544	
Without	3/168 (1.8)	0/169 (0.0)	7.041	(0.367, 135.279)	0.1955	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.2
Adverse Events of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	3 (0.9)	0 (0.0)
Unstratified Analysis		
Odds Ratio	6.980	
95% CI	0.359, 135.633	
p-value	0.1993	
Relative Risk	6.920	
95% CI	0.359, 133.464	
p-value	0.2002	
Risk Difference	0.009	
95% CI	-0.001, 0.018	
p-value	0.0819	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.2.1
Adverse Events of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	2/228 (0.9)	0/226 (0.0)	4.956	(0.239, 102.665)	0.3006	
>= 40 years	1/120 (0.8)	0/118 (0.0)	2.950	(0.121, 71.703)	0.5063	
Geographic regions						NE
US/PR/Canada	0/140 (0.0)	0/131 (0.0)	NE	(NE, NE)	NE	
Other	3/208 (1.4)	0/213 (0.0)	7.167	(0.373, 137.910)	0.1917	
Baseline EASI						1.0000
< Median (26.4)	2/165 (1.2)	0/180 (0.0)	5.452	(0.264, 112.730)	0.2725	
>= Median (26.4)	1/183 (0.5)	0/164 (0.0)	2.690	(0.110, 65.583)	0.5436	
Baseline vIGA-AD						1.0000
3 (Moderate)	2/174 (1.1)	0/171 (0.0)	4.914	(0.238, 101.617)	0.3029	
4 (Severe)	1/174 (0.6)	0/173 (0.0)	2.983	(0.122, 72.719)	0.5024	
Sex						NE
Female	1/165 (0.6)	0/150 (0.0)	2.729	(0.112, 66.481)	0.5377	
Male	2/183 (1.1)	0/194 (0.0)	5.299	(0.256, 109.637)	0.2807	
BMI						1.0000
< 25 kg/m2	2/161 (1.2)	0/169 (0.0)	5.247	(0.254, 108.459)	0.2834	
>= 25 - < 30 kg/m2	0/ 93 (0.0)	0/110 (0.0)	NE	(NE, NE)	NE	
>= 30 kg/m2	1/ 93 (1.1)	0/ 65 (0.0)	2.106	(0.087, 50.910)	0.6466	
Race						NE
White	2/235 (0.9)	0/244 (0.0)	5.191	(0.251, 107.551)	0.2869	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	1/ 36 (2.8)	0/ 22 (0.0)	1.865	(0.079, 43.869)	0.6989	
Baseline hsCRP						NE
< Median (1.745)	2/161 (1.2)	0/185 (0.0)	5.741	(0.278, 118.704)	0.2581	
>= Median(1.745)	1/187 (0.5)	0/159 (0.0)	2.553	(0.105, 62.240)	0.5651	
Previous systemic therapy						NE
With	3/180 (1.7)	0/175 (0.0)	6.807	(0.354, 130.819)	0.2035	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.3
Adverse Events of Special Interest - Herpes zoster
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	12 (3.4)	4 (1.2)
Unstratified Analysis		
Odds Ratio	3.036	
95% CI	0.969, 9.507	
p-value	0.0566	
Relative Risk	2.966	
95% CI	0.966, 9.105	
p-value	0.0575	
Risk Difference	0.023	
95% CI	0.001, 0.045	
p-value	0.0443	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.3.1
Adverse Events of Special Interest - Herpes zoster - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.3716
< 40 years	6/228 (2.6)	3/226 (1.3)	1.982	(0.502, 7.830)	0.3288	
>= 40 years	6/120 (5.0)	1/118 (0.8)	5.900	(0.721, 48.262)	0.0979	
Geographic regions						0.1093
US/PR/Canada	4/140 (2.9)	0/131 (0.0)	8.426	(0.458, 154.988)	0.1514	
Other	8/208 (3.8)	4/213 (1.9)	2.048	(0.626, 6.698)	0.2357	
Baseline EASI						0.6340
< Median (26.4)	4/165 (2.4)	1/180 (0.6)	4.364	(0.493, 38.645)	0.1855	
>= Median (26.4)	8/183 (4.4)	3/164 (1.8)	2.390	(0.645, 8.858)	0.1924	
Baseline vIGA-AD						0.7620
3 (Moderate)	5/174 (2.9)	2/171 (1.2)	2.457	(0.483, 12.492)	0.2786	
4 (Severe)	7/174 (4.0)	2/173 (1.2)	3.480	(0.733, 16.516)	0.1166	
Sex						0.6262
Female	5/165 (3.0)	1/150 (0.7)	4.545	(0.537, 38.465)	0.1647	
Male	7/183 (3.8)	3/194 (1.5)	2.474	(0.649, 9.422)	0.1844	
BMI						0.4583
< 25 kg/m2	8/161 (5.0)	3/169 (1.8)	2.799	(0.756, 10.366)	0.1233	
>= 25 - < 30 kg/m2	1/ 93 (1.1)	1/110 (0.9)	1.183	(0.075, 18.651)	0.9050	
>= 30 kg/m2	3/ 93 (3.2)	0/ 65 (0.0)	4.915	(0.258, 93.568)	0.2895	
Race						0.8088
White	7/235 (3.0)	3/244 (1.2)	2.423	(0.634, 9.258)	0.1958	
Asian	5/ 77 (6.5)	1/ 78 (1.3)	5.065	(0.606, 42.358)	0.1343	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						0.2430
< Median (1.745)	9/161 (5.6)	2/185 (1.1)	5.171	(1.134, 23.584)	0.0338	
>= Median(1.745)	3/187 (1.6)	2/159 (1.3)	1.275	(0.216, 7.538)	0.7884	
Previous systemic therapy						0.9762
With	6/180 (3.3)	2/175 (1.1)	2.917	(0.597, 14.256)	0.1861	
Without	6/168 (3.6)	2/169 (1.2)	3.018	(0.618, 14.740)	0.1723	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.4
Adverse Events of Special Interest - Active tuberculosis
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.4.1
Adverse Events of Special Interest - Active tuberculosis - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	0/120 (0.0)	0/118 (0.0)	NE	(NE, NE)	NE	
Geographic regions						NE
US/PR/Canada	0/140 (0.0)	0/131 (0.0)	NE	(NE, NE)	NE	
Other	0/208 (0.0)	0/213 (0.0)	NE	(NE, NE)	NE	
Baseline EASI						NE
< Median (26.4)	0/165 (0.0)	0/180 (0.0)	NE	(NE, NE)	NE	
>= Median (26.4)	0/183 (0.0)	0/164 (0.0)	NE	(NE, NE)	NE	
Baseline vIGA-AD						NE
3 (Moderate)	0/174 (0.0)	0/171 (0.0)	NE	(NE, NE)	NE	
4 (Severe)	0/174 (0.0)	0/173 (0.0)	NE	(NE, NE)	NE	
Sex						NE
Female	0/165 (0.0)	0/150 (0.0)	NE	(NE, NE)	NE	
Male	0/183 (0.0)	0/194 (0.0)	NE	(NE, NE)	NE	
BMI						NE
< 25 kg/m2	0/161 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	
>= 25 - < 30 kg/m2	0/ 93 (0.0)	0/110 (0.0)	NE	(NE, NE)	NE	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	0/235 (0.0)	0/244 (0.0)	NE	(NE, NE)	NE	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						NE
< Median (1.745)	0/161 (0.0)	0/185 (0.0)	NE	(NE, NE)	NE	
>= Median(1.745)	0/187 (0.0)	0/159 (0.0)	NE	(NE, NE)	NE	
Previous systemic therapy						NE
With	0/180 (0.0)	0/175 (0.0)	NE	(NE, NE)	NE	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.5
Adverse Events of Special Interest - Possible malignancy
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	1 (0.3)
Unstratified Analysis		
Odds Ratio	0.988	
95% CI	0.062, 15.867	
p-value	0.9935	
Relative Risk	0.989	
95% CI	0.062, 15.741	
p-value	0.9935	
Risk Difference	-0.000	
95% CI	-0.008, 0.008	
p-value	0.9935	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.5.1
Adverse Events of Special Interest - Possible malignancy - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	1/120 (0.8)	1/118 (0.8)	0.983	(0.062, 15.539)	0.9905	
Geographic regions						0.1010
US/PR/Canada	1/140 (0.7)	0/131 (0.0)	2.809	(0.115, 68.337)	0.5260	
Other	0/208 (0.0)	1/213 (0.5)	0.341	(0.014, 8.331)	0.5096	
Baseline EASI						0.1078
< Median (26.4)	0/165 (0.0)	1/180 (0.6)	0.363	(0.015, 8.860)	0.5345	
>= Median (26.4)	1/183 (0.5)	0/164 (0.0)	2.690	(0.110, 65.583)	0.5436	
Baseline vIGA-AD						0.0949
3 (Moderate)	0/174 (0.0)	1/171 (0.6)	0.328	(0.013, 7.987)	0.4935	
4 (Severe)	1/174 (0.6)	0/173 (0.0)	2.983	(0.122, 72.719)	0.5024	
Sex						0.1050
Female	1/165 (0.6)	0/150 (0.0)	2.729	(0.112, 66.481)	0.5377	
Male	0/183 (0.0)	1/194 (0.5)	0.353	(0.014, 8.617)	0.5232	
BMI						NE
< 25 kg/m2	0/161 (0.0)	1/169 (0.6)	0.350	(0.014, 8.525)	0.5191	
>= 25 - < 30 kg/m2	1/ 93 (1.1)	0/110 (0.0)	3.543	(0.146, 85.939)	0.4369	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	1/235 (0.4)	1/244 (0.4)	1.038	(0.065, 16.504)	0.9788	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						0.1147
< Median (1.745)	0/161 (0.0)	1/185 (0.5)	0.383	(0.016, 9.330)	0.5556	
>= Median(1.745)	1/187 (0.5)	0/159 (0.0)	2.553	(0.105, 62.240)	0.5651	
Previous systemic therapy						1.0000
With	1/180 (0.6)	1/175 (0.6)	0.972	(0.061, 15.422)	0.9841	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.6
Adverse Events of Special Interest - Malignancy
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	1 (0.3)
Unstratified Analysis		
Odds Ratio	0.988	
95% CI	0.062, 15.867	
p-value	0.9935	
Relative Risk	0.989	
95% CI	0.062, 15.741	
p-value	0.9935	
Risk Difference	-0.000	
95% CI	-0.008, 0.008	
p-value	0.9935	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.6.1
Adverse Events of Special Interest - Malignancy - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	1/120 (0.8)	1/118 (0.8)	0.983	(0.062, 15.539)	0.9905	
Geographic regions						0.1010
US/PR/Canada	1/140 (0.7)	0/131 (0.0)	2.809	(0.115, 68.337)	0.5260	
Other	0/208 (0.0)	1/213 (0.5)	0.341	(0.014, 8.331)	0.5096	
Baseline EASI						0.1078
< Median (26.4)	0/165 (0.0)	1/180 (0.6)	0.363	(0.015, 8.860)	0.5345	
>= Median (26.4)	1/183 (0.5)	0/164 (0.0)	2.690	(0.110, 65.583)	0.5436	
Baseline vIGA-AD						0.0949
3 (Moderate)	0/174 (0.0)	1/171 (0.6)	0.328	(0.013, 7.987)	0.4935	
4 (Severe)	1/174 (0.6)	0/173 (0.0)	2.983	(0.122, 72.719)	0.5024	
Sex						0.1050
Female	1/165 (0.6)	0/150 (0.0)	2.729	(0.112, 66.481)	0.5377	
Male	0/183 (0.0)	1/194 (0.5)	0.353	(0.014, 8.617)	0.5232	
BMI						NE
< 25 kg/m2	0/161 (0.0)	1/169 (0.6)	0.350	(0.014, 8.525)	0.5191	
>= 25 - < 30 kg/m2	1/ 93 (1.1)	0/110 (0.0)	3.543	(0.146, 85.939)	0.4369	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	1/235 (0.4)	1/244 (0.4)	1.038	(0.065, 16.504)	0.9788	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						0.1147
< Median (1.745)	0/161 (0.0)	1/185 (0.5)	0.383	(0.016, 9.330)	0.5556	
>= Median(1.745)	1/187 (0.5)	0/159 (0.0)	2.553	(0.105, 62.240)	0.5651	
Previous systemic therapy						1.0000
With	1/180 (0.6)	1/175 (0.6)	0.972	(0.061, 15.422)	0.9841	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.7
Adverse Events of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Unstratified Analysis		
Odds Ratio	0.329	
95% CI	0.013, 8.093	
p-value	0.4960	
Relative Risk	0.330	
95% CI	0.013, 8.061	
p-value	0.4962	
Risk Difference	-0.003	
95% CI	-0.009, 0.003	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.7.1
Adverse Events of Special Interest - Non-melanoma skin cancer (NMSC) - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	0/120 (0.0)	1/118 (0.8)	0.328	(0.013, 7.967)	0.4933	
Geographic regions						NE
US/PR/Canada	0/140 (0.0)	0/131 (0.0)	NE	(NE, NE)	NE	
Other	0/208 (0.0)	1/213 (0.5)	0.341	(0.014, 8.331)	0.5096	
Baseline EASI						NE
< Median (26.4)	0/165 (0.0)	1/180 (0.6)	0.363	(0.015, 8.860)	0.5345	
>= Median (26.4)	0/183 (0.0)	0/164 (0.0)	NE	(NE, NE)	NE	
Baseline vIGA-AD						NE
3 (Moderate)	0/174 (0.0)	1/171 (0.6)	0.328	(0.013, 7.987)	0.4935	
4 (Severe)	0/174 (0.0)	0/173 (0.0)	NE	(NE, NE)	NE	
Sex						NE
Female	0/165 (0.0)	0/150 (0.0)	NE	(NE, NE)	NE	
Male	0/183 (0.0)	1/194 (0.5)	0.353	(0.014, 8.617)	0.5232	
BMI						NE
< 25 kg/m2	0/161 (0.0)	1/169 (0.6)	0.350	(0.014, 8.525)	0.5191	
>= 25 - < 30 kg/m2	0/ 93 (0.0)	0/110 (0.0)	NE	(NE, NE)	NE	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	0/235 (0.0)	1/244 (0.4)	0.346	(0.014, 8.452)	0.5151	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						NE
< Median (1.745)	0/161 (0.0)	1/185 (0.5)	0.383	(0.016, 9.330)	0.5556	
>= Median(1.745)	0/187 (0.0)	0/159 (0.0)	NE	(NE, NE)	NE	
Previous systemic therapy						NE
With	0/180 (0.0)	1/175 (0.6)	0.324	(0.013, 7.903)	0.4893	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.8
Adverse Events of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.8.1
Adverse Events of Special Interest - Malignancy other than NMSC - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	1/120 (0.8)	0/118 (0.0)	2.950	(0.121, 71.703)	0.5063	
Geographic regions						NE
US/PR/Canada	1/140 (0.7)	0/131 (0.0)	2.809	(0.115, 68.337)	0.5260	
Other	0/208 (0.0)	0/213 (0.0)	NE	(NE, NE)	NE	
Baseline EASI						NE
< Median (26.4)	0/165 (0.0)	0/180 (0.0)	NE	(NE, NE)	NE	
>= Median (26.4)	1/183 (0.5)	0/164 (0.0)	2.690	(0.110, 65.583)	0.5436	
Baseline vIGA-AD						NE
3 (Moderate)	0/174 (0.0)	0/171 (0.0)	NE	(NE, NE)	NE	
4 (Severe)	1/174 (0.6)	0/173 (0.0)	2.983	(0.122, 72.719)	0.5024	
Sex						NE
Female	1/165 (0.6)	0/150 (0.0)	2.729	(0.112, 66.481)	0.5377	
Male	0/183 (0.0)	0/194 (0.0)	NE	(NE, NE)	NE	
BMI						1.0000
< 25 kg/m2	0/161 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	
>= 25 - < 30 kg/m2	1/ 93 (1.1)	0/110 (0.0)	3.543	(0.146, 85.939)	0.4369	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	1/235 (0.4)	0/244 (0.0)	3.114	(0.128, 76.070)	0.4859	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						NE
< Median (1.745)	0/161 (0.0)	0/185 (0.0)	NE	(NE, NE)	NE	
>= Median(1.745)	1/187 (0.5)	0/159 (0.0)	2.553	(0.105, 62.240)	0.5651	
Previous systemic therapy						NE
With	1/180 (0.6)	0/175 (0.0)	2.917	(0.120, 71.128)	0.5112	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.9
Adverse Events of Special Interest - Lymphoma
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.9.1
Adverse Events of Special Interest - Lymphoma - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	0/120 (0.0)	0/118 (0.0)	NE	(NE, NE)	NE	
Geographic regions						NE
US/PR/Canada	0/140 (0.0)	0/131 (0.0)	NE	(NE, NE)	NE	
Other	0/208 (0.0)	0/213 (0.0)	NE	(NE, NE)	NE	
Baseline EASI						NE
< Median (26.4)	0/165 (0.0)	0/180 (0.0)	NE	(NE, NE)	NE	
>= Median (26.4)	0/183 (0.0)	0/164 (0.0)	NE	(NE, NE)	NE	
Baseline vIGA-AD						NE
3 (Moderate)	0/174 (0.0)	0/171 (0.0)	NE	(NE, NE)	NE	
4 (Severe)	0/174 (0.0)	0/173 (0.0)	NE	(NE, NE)	NE	
Sex						NE
Female	0/165 (0.0)	0/150 (0.0)	NE	(NE, NE)	NE	
Male	0/183 (0.0)	0/194 (0.0)	NE	(NE, NE)	NE	
BMI						NE
< 25 kg/m2	0/161 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	
>= 25 - < 30 kg/m2	0/ 93 (0.0)	0/110 (0.0)	NE	(NE, NE)	NE	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	0/235 (0.0)	0/244 (0.0)	NE	(NE, NE)	NE	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						NE
< Median (1.745)	0/161 (0.0)	0/185 (0.0)	NE	(NE, NE)	NE	
>= Median(1.745)	0/187 (0.0)	0/159 (0.0)	NE	(NE, NE)	NE	
Previous systemic therapy						NE
With	0/180 (0.0)	0/175 (0.0)	NE	(NE, NE)	NE	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.10
Adverse Events of Special Interest - Hepatic disorder
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	12 (3.4)	5 (1.5)
Unstratified Analysis		
Odds Ratio	2.421	
95% CI	0.844, 6.948	
p-value	0.1001	
Relative Risk	2.372	
95% CI	0.845, 6.662	
p-value	0.1010	
Risk Difference	0.020	
95% CI	-0.003, 0.043	
p-value	0.0887	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.10.1
Adverse Events of Special Interest - Hepatic disorder - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.5747
< 40 years	8/228 (3.5)	4/226 (1.8)	1.982	(0.605, 6.491)	0.2581	
>= 40 years	4/120 (3.3)	1/118 (0.8)	3.933	(0.446, 34.675)	0.2175	
Geographic regions						0.1566
US/PR/Canada	7/140 (5.0)	1/131 (0.8)	6.550	(0.817, 52.518)	0.0768	
Other	5/208 (2.4)	4/213 (1.9)	1.280	(0.349, 4.701)	0.7099	
Baseline EASI						0.1703
< Median (26.4)	6/165 (3.6)	1/180 (0.6)	6.545	(0.796, 53.796)	0.0804	
>= Median (26.4)	6/183 (3.3)	4/164 (2.4)	1.344	(0.386, 4.680)	0.6421	
Baseline vIGA-AD						0.9574
3 (Moderate)	5/174 (2.9)	2/171 (1.2)	2.457	(0.483, 12.492)	0.2786	
4 (Severe)	7/174 (4.0)	3/173 (1.7)	2.320	(0.610, 8.825)	0.2170	
Sex						0.0481
Female	5/165 (3.0)	0/150 (0.0)	10.006	(0.558, 179.440)	0.1179	
Male	7/183 (3.8)	5/194 (2.6)	1.484	(0.480, 4.593)	0.4933	
BMI						0.4022
< 25 kg/m2	4/161 (2.5)	3/169 (1.8)	1.400	(0.318, 6.156)	0.6565	
>= 25 - < 30 kg/m2	3/ 93 (3.2)	1/110 (0.9)	3.548	(0.375, 33.541)	0.2691	
>= 30 kg/m2	5/ 93 (5.4)	1/ 65 (1.5)	3.495	(0.418, 29.217)	0.2482	
Race						0.4515
White	6/235 (2.6)	3/244 (1.2)	2.077	(0.525, 8.207)	0.2973	
Asian	3/ 77 (3.9)	2/ 78 (2.6)	1.519	(0.261, 8.843)	0.6415	
Other	3/ 36 (8.3)	0/ 22 (0.0)	4.351	(0.235, 80.448)	0.3232	
Baseline hsCRP						0.9901
< Median (1.745)	4/161 (2.5)	2/185 (1.1)	2.298	(0.427, 12.382)	0.3329	
>= Median(1.745)	8/187 (4.3)	3/159 (1.9)	2.267	(0.612, 8.403)	0.2206	
Previous systemic therapy						0.4652
With	5/180 (2.8)	3/175 (1.7)	1.620	(0.393, 6.678)	0.5041	
Without	7/168 (4.2)	2/169 (1.2)	3.521	(0.742, 16.703)	0.1131	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.11
Adverse Events of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.11.1
Adverse Events of Special Interest - Adjudicated gastrointestinal perforation - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	0/120 (0.0)	0/118 (0.0)	NE	(NE, NE)	NE	
Geographic regions						NE
US/PR/Canada	0/140 (0.0)	0/131 (0.0)	NE	(NE, NE)	NE	
Other	0/208 (0.0)	0/213 (0.0)	NE	(NE, NE)	NE	
Baseline EASI						NE
< Median (26.4)	0/165 (0.0)	0/180 (0.0)	NE	(NE, NE)	NE	
>= Median (26.4)	0/183 (0.0)	0/164 (0.0)	NE	(NE, NE)	NE	
Baseline vIGA-AD						NE
3 (Moderate)	0/174 (0.0)	0/171 (0.0)	NE	(NE, NE)	NE	
4 (Severe)	0/174 (0.0)	0/173 (0.0)	NE	(NE, NE)	NE	
Sex						NE
Female	0/165 (0.0)	0/150 (0.0)	NE	(NE, NE)	NE	
Male	0/183 (0.0)	0/194 (0.0)	NE	(NE, NE)	NE	
BMI						NE
< 25 kg/m2	0/161 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	
>= 25 - < 30 kg/m2	0/ 93 (0.0)	0/110 (0.0)	NE	(NE, NE)	NE	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	0/235 (0.0)	0/244 (0.0)	NE	(NE, NE)	NE	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						NE
< Median (1.745)	0/161 (0.0)	0/185 (0.0)	NE	(NE, NE)	NE	
>= Median(1.745)	0/187 (0.0)	0/159 (0.0)	NE	(NE, NE)	NE	
Previous systemic therapy						NE
With	0/180 (0.0)	0/175 (0.0)	NE	(NE, NE)	NE	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.12
Adverse Events of Special Interest - Anemia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	8 (2.3)	1 (0.3)
Unstratified Analysis		
Odds Ratio	8.071	
95% CI	1.004, 64.877	
p-value	0.0496	
Relative Risk	7.908	
95% CI	0.994, 62.890	
p-value	0.0506	
Risk Difference	0.020	
95% CI	0.003, 0.037	
p-value	0.0187	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.12.1
Adverse Events of Special Interest - Anemia - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.2592
< 40 years	4/228 (1.8)	1/226 (0.4)	3.965	(0.447, 35.200)	0.2163	
>= 40 years	4/120 (3.3)	0/118 (0.0)	8.851	(0.482, 162.605)	0.1420	
Geographic regions						0.2432
US/PR/Canada	4/140 (2.9)	1/131 (0.8)	3.743	(0.424, 33.055)	0.2350	
Other	4/208 (1.9)	0/213 (0.0)	9.215	(0.499, 170.100)	0.1354	
Baseline EASI						0.2093
< Median (26.4)	3/165 (1.8)	1/180 (0.6)	3.273	(0.344, 31.153)	0.3024	
>= Median (26.4)	5/183 (2.7)	0/164 (0.0)	9.864	(0.550, 177.031)	0.1203	
Baseline vIGA-AD						0.2561
3 (Moderate)	4/174 (2.3)	1/171 (0.6)	3.931	(0.444, 34.814)	0.2187	
4 (Severe)	4/174 (2.3)	0/173 (0.0)	8.949	(0.485, 164.958)	0.1405	
Sex						0.2331
Female	4/165 (2.4)	1/150 (0.7)	3.636	(0.411, 32.172)	0.2458	
Male	4/183 (2.2)	0/194 (0.0)	9.538	(0.517, 175.929)	0.1294	
BMI						NE
< 25 kg/m2	3/161 (1.9)	1/169 (0.6)	3.149	(0.331, 29.963)	0.3183	
>= 25 - < 30 kg/m2	2/ 93 (2.2)	0/110 (0.0)	5.904	(0.287, 121.460)	0.2498	
>= 30 kg/m2	3/ 93 (3.2)	0/ 65 (0.0)	4.915	(0.258, 93.568)	0.2895	
Race						NE
White	3/235 (1.3)	1/244 (0.4)	3.115	(0.326, 29.733)	0.3236	
Asian	3/ 77 (3.9)	0/ 78 (0.0)	7.090	(0.372, 135.000)	0.1926	
Other	2/ 36 (5.6)	0/ 22 (0.0)	3.108	(0.156, 61.895)	0.4575	
Baseline hsCRP						0.3101
< Median (1.745)	4/161 (2.5)	1/185 (0.5)	4.596	(0.519, 40.705)	0.1705	
>= Median(1.745)	4/187 (2.1)	0/159 (0.0)	7.660	(0.416, 141.187)	0.1709	
Previous systemic therapy						0.3559
With	3/180 (1.7)	0/175 (0.0)	6.807	(0.354, 130.819)	0.2035	
Without	5/168 (3.0)	1/169 (0.6)	5.030	(0.594, 42.596)	0.1383	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.13
Adverse Events of Special Interest - Neutropenia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	6 (1.7)	2 (0.6)
Unstratified Analysis		
Odds Ratio	3.000	
95% CI	0.601, 14.968	
p-value	0.1804	
Relative Risk	2.966	
95% CI	0.603, 14.591	
p-value	0.1812	
Risk Difference	0.011	
95% CI	-0.004, 0.027	
p-value	0.1579	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Upadacitinib (M16-046) - (Final Datacut) Final
Table 3.1.10.13.1
Adverse Events of Special Interest - Neutropenia - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.0221
< 40 years	5/228 (2.2)	0/226 (0.0)	10.904	(0.606, 196.047)	0.1051	
>= 40 years	1/120 (0.8)	2/118 (1.7)	0.492	(0.045, 5.350)	0.5599	
Geographic regions						0.3382
US/PR/Canada	1/140 (0.7)	1/131 (0.8)	0.936	(0.059, 14.807)	0.9624	
Other	5/208 (2.4)	1/213 (0.5)	5.120	(0.603, 43.454)	0.1344	
Baseline EASI						0.2778
< Median (26.4)	4/165 (2.4)	2/180 (1.1)	2.182	(0.405, 11.756)	0.3639	
>= Median (26.4)	2/183 (1.1)	0/164 (0.0)	4.484	(0.217, 92.715)	0.3316	
Baseline vIGA-AD						0.9943
3 (Moderate)	3/174 (1.7)	1/171 (0.6)	2.948	(0.310, 28.065)	0.3470	
4 (Severe)	3/174 (1.7)	1/173 (0.6)	2.983	(0.313, 28.395)	0.3418	
Sex						0.6091
Female	2/165 (1.2)	1/150 (0.7)	1.818	(0.167, 19.848)	0.6240	
Male	4/183 (2.2)	1/194 (0.5)	4.240	(0.478, 37.587)	0.1944	
BMI						0.2198
< 25 kg/m2	4/161 (2.5)	1/169 (0.6)	4.199	(0.474, 37.168)	0.1972	
>= 25 - < 30 kg/m2	2/ 93 (2.2)	0/110 (0.0)	5.904	(0.287, 121.460)	0.2498	
>= 30 kg/m2	0/ 93 (0.0)	1/ 65 (1.5)	0.234	(0.010, 5.657)	0.3715	
Race						NE
White	4/235 (1.7)	2/244 (0.8)	2.077	(0.384, 11.230)	0.3962	
Asian	1/ 77 (1.3)	0/ 78 (0.0)	3.038	(0.126, 73.452)	0.4941	
Other	1/ 36 (2.8)	0/ 22 (0.0)	1.865	(0.079, 43.869)	0.6989	
Baseline hsCRP						0.2831
< Median (1.745)	5/161 (3.1)	1/185 (0.5)	5.745	(0.678, 48.667)	0.1088	
>= Median(1.745)	1/187 (0.5)	1/159 (0.6)	0.850	(0.054, 13.484)	0.9084	
Previous systemic therapy						0.9833
With	3/180 (1.7)	1/175 (0.6)	2.917	(0.306, 27.772)	0.3519	
Without	3/168 (1.8)	1/169 (0.6)	3.018	(0.317, 28.721)	0.3366	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.14
Adverse Events of Special Interest - Lymphopenia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	2 (0.6)	0 (0.0)
Unstratified Analysis		
Odds Ratio	4.971	
95% CI	0.238, 103.925	
p-value	0.3012	
Relative Risk	4.943	
95% CI	0.238, 102.578	
p-value	0.3018	
Risk Difference	0.006	
95% CI	-0.002, 0.014	
p-value	0.1561	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.14.1
Adverse Events of Special Interest - Lymphopenia - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	2/228 (0.9)	0/226 (0.0)	4.956	(0.239, 102.665)	0.3006	
>= 40 years	0/120 (0.0)	0/118 (0.0)	NE	(NE, NE)	NE	
Geographic regions						NE
US/PR/Canada	0/140 (0.0)	0/131 (0.0)	NE	(NE, NE)	NE	
Other	2/208 (1.0)	0/213 (0.0)	5.120	(0.247, 106.002)	0.2909	
Baseline EASI						NE
< Median (26.4)	0/165 (0.0)	0/180 (0.0)	NE	(NE, NE)	NE	
>= Median (26.4)	2/183 (1.1)	0/164 (0.0)	4.484	(0.217, 92.715)	0.3316	
Baseline vIGA-AD						1.0000
3 (Moderate)	1/174 (0.6)	0/171 (0.0)	2.949	(0.121, 71.880)	0.5069	
4 (Severe)	1/174 (0.6)	0/173 (0.0)	2.983	(0.122, 72.719)	0.5024	
Sex						NE
Female	2/165 (1.2)	0/150 (0.0)	4.548	(0.220, 93.980)	0.3269	
Male	0/183 (0.0)	0/194 (0.0)	NE	(NE, NE)	NE	
BMI						1.0000
< 25 kg/m2	1/161 (0.6)	0/169 (0.0)	3.148	(0.129, 76.721)	0.4815	
>= 25 - < 30 kg/m2	1/ 93 (1.1)	0/110 (0.0)	3.543	(0.146, 85.939)	0.4369	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	2/235 (0.9)	0/244 (0.0)	5.191	(0.251, 107.551)	0.2869	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						1.0000
< Median (1.745)	1/161 (0.6)	0/185 (0.0)	3.444	(0.141, 83.968)	0.4478	
>= Median(1.745)	1/187 (0.5)	0/159 (0.0)	2.553	(0.105, 62.240)	0.5651	
Previous systemic therapy						NE
With	0/180 (0.0)	0/175 (0.0)	NE	(NE, NE)	NE	
Without	2/168 (1.2)	0/169 (0.0)	5.030	(0.243, 103.983)	0.2959	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.15
Adverse Events of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	26 (7.5)	11 (3.2)
Unstratified Analysis		
Odds Ratio	2.444	
95% CI	1.188, 5.029	
p-value	0.0152	
Relative Risk	2.336	
95% CI	1.173, 4.654	
p-value	0.0158	
Risk Difference	0.043	
95% CI	0.009, 0.076	
p-value	0.0119	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.15.1
Adverse Events of Special Interest - Creatine phosphokinase (CPK) elevation - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.1963
< 40 years	19/228 (8.3)	10/226 (4.4)	1.883	(0.896, 3.960)	0.0951	
>= 40 years	7/120 (5.8)	1/118 (0.8)	6.883	(0.860, 55.088)	0.0691	
Geographic regions						0.0405
US/PR/Canada	11/140 (7.9)	1/131 (0.8)	10.293	(1.347, 78.622)	0.0246	
Other	15/208 (7.2)	10/213 (4.7)	1.536	(0.706, 3.341)	0.2789	
Baseline EASI						0.2451
< Median (26.4)	10/165 (6.1)	7/180 (3.9)	1.558	(0.607, 4.000)	0.3562	
>= Median (26.4)	16/183 (8.7)	4/164 (2.4)	3.585	(1.223, 10.505)	0.0200	
Baseline vIGA-AD						0.0027
3 (Moderate)	8/174 (4.6)	9/171 (5.3)	0.874	(0.345, 2.211)	0.7754	
4 (Severe)	18/174 (10.3)	2/173 (1.2)	8.948	(2.108, 37.981)	0.0030	
Sex						0.9835
Female	8/165 (4.8)	3/150 (2.0)	2.424	(0.655, 8.970)	0.1847	
Male	18/183 (9.8)	8/194 (4.1)	2.385	(1.063, 5.351)	0.0350	
BMI						0.0120
< 25 kg/m2	9/161 (5.6)	10/169 (5.9)	0.945	(0.394, 2.265)	0.8986	
>= 25 - < 30 kg/m2	11/ 93 (11.8)	0/110 (0.0)	27.160	(1.622, 454.771)	0.0217	
>= 30 kg/m2	6/ 93 (6.5)	1/ 65 (1.5)	4.194	(0.517, 34.012)	0.1795	
Race						0.3090
White	14/235 (6.0)	5/244 (2.0)	2.907	(1.064, 7.945)	0.0375	
Asian	6/ 77 (7.8)	3/ 78 (3.8)	2.026	(0.525, 7.812)	0.3052	
Other	6/ 36 (16.7)	3/ 22 (13.6)	1.222	(0.340, 4.398)	0.7587	
Baseline hsCRP						0.5002
< Median (1.745)	17/161 (10.6)	9/185 (4.9)	2.170	(0.995, 4.734)	0.0515	
>= Median(1.745)	9/187 (4.8)	2/159 (1.3)	3.826	(0.839, 17.451)	0.0831	
Previous systemic therapy						0.7586
With	13/180 (7.2)	6/175 (3.4)	2.106	(0.819, 5.418)	0.1222	
Without	13/168 (7.7)	5/169 (3.0)	2.615	(0.954, 7.174)	0.0618	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.16
Adverse Events of Special Interest - Renal dysfunction
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	1 (0.3)
Unstratified Analysis		
Odds Ratio	0.988	
95% CI	0.062, 15.867	
p-value	0.9935	
Relative Risk	0.989	
95% CI	0.062, 15.741	
p-value	0.9935	
Risk Difference	-0.000	
95% CI	-0.008, 0.008	
p-value	0.9935	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.16.1
Adverse Events of Special Interest - Renal dysfunction - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	1/120 (0.8)	1/118 (0.8)	0.983	(0.062, 15.539)	0.9905	
Geographic regions						0.1010
US/PR/Canada	1/140 (0.7)	0/131 (0.0)	2.809	(0.115, 68.337)	0.5260	
Other	0/208 (0.0)	1/213 (0.5)	0.341	(0.014, 8.331)	0.5096	
Baseline EASI						1.0000
< Median (26.4)	0/165 (0.0)	0/180 (0.0)	NE	(NE, NE)	NE	
>= Median (26.4)	1/183 (0.5)	1/164 (0.6)	0.896	(0.057, 14.213)	0.9380	
Baseline vIGA-AD						1.0000
3 (Moderate)	1/174 (0.6)	1/171 (0.6)	0.983	(0.062, 15.586)	0.9902	
4 (Severe)	0/174 (0.0)	0/173 (0.0)	NE	(NE, NE)	NE	
Sex						1.0000
Female	1/165 (0.6)	1/150 (0.7)	0.909	(0.057, 14.406)	0.9461	
Male	0/183 (0.0)	0/194 (0.0)	NE	(NE, NE)	NE	
BMI						NE
< 25 kg/m2	0/161 (0.0)	1/169 (0.6)	0.350	(0.014, 8.525)	0.5191	
>= 25 - < 30 kg/m2	0/ 93 (0.0)	0/110 (0.0)	NE	(NE, NE)	NE	
>= 30 kg/m2	1/ 93 (1.1)	0/ 65 (0.0)	2.106	(0.087, 50.910)	0.6466	
Race						NE
White	0/235 (0.0)	0/244 (0.0)	NE	(NE, NE)	NE	
Asian	0/ 77 (0.0)	1/ 78 (1.3)	0.338	(0.014, 8.161)	0.5040	
Other	1/ 36 (2.8)	0/ 22 (0.0)	1.865	(0.079, 43.869)	0.6989	
Baseline hsCRP						0.1147
< Median (1.745)	0/161 (0.0)	1/185 (0.5)	0.383	(0.016, 9.330)	0.5556	
>= Median(1.745)	1/187 (0.5)	0/159 (0.0)	2.553	(0.105, 62.240)	0.5651	
Previous systemic therapy						0.0935
With	0/180 (0.0)	1/175 (0.6)	0.324	(0.013, 7.903)	0.4893	
Without	1/168 (0.6)	0/169 (0.0)	3.018	(0.124, 73.555)	0.4979	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.17
Adverse Events of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.17.1
Adverse Events of Special Interest - Adjudicated major adverse cardiovascular events (MACE) - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	0/120 (0.0)	0/118 (0.0)	NE	(NE, NE)	NE	
Geographic regions						NE
US/PR/Canada	0/140 (0.0)	0/131 (0.0)	NE	(NE, NE)	NE	
Other	0/208 (0.0)	0/213 (0.0)	NE	(NE, NE)	NE	
Baseline EASI						NE
< Median (26.4)	0/165 (0.0)	0/180 (0.0)	NE	(NE, NE)	NE	
>= Median (26.4)	0/183 (0.0)	0/164 (0.0)	NE	(NE, NE)	NE	
Baseline vIGA-AD						NE
3 (Moderate)	0/174 (0.0)	0/171 (0.0)	NE	(NE, NE)	NE	
4 (Severe)	0/174 (0.0)	0/173 (0.0)	NE	(NE, NE)	NE	
Sex						NE
Female	0/165 (0.0)	0/150 (0.0)	NE	(NE, NE)	NE	
Male	0/183 (0.0)	0/194 (0.0)	NE	(NE, NE)	NE	
BMI						NE
< 25 kg/m2	0/161 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	
>= 25 - < 30 kg/m2	0/ 93 (0.0)	0/110 (0.0)	NE	(NE, NE)	NE	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	0/235 (0.0)	0/244 (0.0)	NE	(NE, NE)	NE	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						NE
< Median (1.745)	0/161 (0.0)	0/185 (0.0)	NE	(NE, NE)	NE	
>= Median(1.745)	0/187 (0.0)	0/159 (0.0)	NE	(NE, NE)	NE	
Previous systemic therapy						NE
With	0/180 (0.0)	0/175 (0.0)	NE	(NE, NE)	NE	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.10.18
Adverse Events of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.10.18.1
Adverse Events of Special Interest - Adjudicated venous thromboembolic events (VTE) - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						NE
< 40 years	0/228 (0.0)	0/226 (0.0)	NE	(NE, NE)	NE	
>= 40 years	0/120 (0.0)	0/118 (0.0)	NE	(NE, NE)	NE	
Geographic regions						NE
US/PR/Canada	0/140 (0.0)	0/131 (0.0)	NE	(NE, NE)	NE	
Other	0/208 (0.0)	0/213 (0.0)	NE	(NE, NE)	NE	
Baseline EASI						NE
< Median (26.4)	0/165 (0.0)	0/180 (0.0)	NE	(NE, NE)	NE	
>= Median (26.4)	0/183 (0.0)	0/164 (0.0)	NE	(NE, NE)	NE	
Baseline vIGA-AD						NE
3 (Moderate)	0/174 (0.0)	0/171 (0.0)	NE	(NE, NE)	NE	
4 (Severe)	0/174 (0.0)	0/173 (0.0)	NE	(NE, NE)	NE	
Sex						NE
Female	0/165 (0.0)	0/150 (0.0)	NE	(NE, NE)	NE	
Male	0/183 (0.0)	0/194 (0.0)	NE	(NE, NE)	NE	
BMI						NE
< 25 kg/m2	0/161 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	
>= 25 - < 30 kg/m2	0/ 93 (0.0)	0/110 (0.0)	NE	(NE, NE)	NE	
>= 30 kg/m2	0/ 93 (0.0)	0/ 65 (0.0)	NE	(NE, NE)	NE	
Race						NE
White	0/235 (0.0)	0/244 (0.0)	NE	(NE, NE)	NE	
Asian	0/ 77 (0.0)	0/ 78 (0.0)	NE	(NE, NE)	NE	
Other	0/ 36 (0.0)	0/ 22 (0.0)	NE	(NE, NE)	NE	
Baseline hsCRP						NE
< Median (1.745)	0/161 (0.0)	0/185 (0.0)	NE	(NE, NE)	NE	
>= Median(1.745)	0/187 (0.0)	0/159 (0.0)	NE	(NE, NE)	NE	
Previous systemic therapy						NE
With	0/180 (0.0)	0/175 (0.0)	NE	(NE, NE)	NE	
Without	0/168 (0.0)	0/169 (0.0)	NE	(NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.11.1
Serious Adverse Events of Special Interest - Serious Infection
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	4 (1.1)	2 (0.6)
Unstratified Analysis		
Odds Ratio	1.988	
95% CI	0.362, 10.927	
p-value	0.4292	
Relative Risk	1.977	
95% CI	0.364, 10.723	
p-value	0.4295	
Risk Difference	0.006	
95% CI	-0.008, 0.019	
p-value	0.4192	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.2
Serious Adverse Events of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.3
Serious Adverse Events of Special Interest - Herpes zoster
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.4
Serious Adverse Events of Special Interest - Active tuberculosis
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.5
Serious Adverse Events of Special Interest - Possible malignancy
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.6
Serious Adverse Events of Special Interest - Malignancy
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.7
Serious Adverse Events of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.8
Serious Adverse Events of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.9
Serious Adverse Events of Special Interest - Lymphoma
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.10
Serious Adverse Events of Special Interest - Hepatic disorder
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.11
Serious Adverse Events of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.12
Serious Adverse Events of Special Interest - Anemia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.13
Serious Adverse Events of Special Interest - Neutropenia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.14
Serious Adverse Events of Special Interest - Lymphopenia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.15
Serious Adverse Events of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Unstratified Analysis		
Odds Ratio	0.329	
95% CI	0.013, 8.093	
p-value	0.4960	
Relative Risk	0.330	
95% CI	0.013, 8.061	
p-value	0.4962	
Risk Difference	-0.003	
95% CI	-0.009, 0.003	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.16
Serious Adverse Events of Special Interest - Renal dysfunction
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.17
Serious Adverse Events of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.11.18
Serious Adverse Events of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.1
Adverse Events of Special Interest of CTCAE Grade >=3 - Serious Infection
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	4 (1.1)	2 (0.6)
Unstratified Analysis		
Odds Ratio	1.988	
95% CI	0.362, 10.927	
p-value	0.4292	
Relative Risk	1.977	
95% CI	0.364, 10.723	
p-value	0.4295	
Risk Difference	0.006	
95% CI	-0.008, 0.019	
p-value	0.4192	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.2
Adverse Events of Special Interest of CTCAE Grade >=3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.3
Adverse Events of Special Interest of CTCAE Grade >=3 - Herpes zoster
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.4
Adverse Events of Special Interest of CTCAE Grade >=3 - Active tuberculosis
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.5
Adverse Events of Special Interest of CTCAE Grade >=3 - Possible malignancy
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.6
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.7
Adverse Events of Special Interest of CTCAE Grade >=3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.8
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy other than NMSC
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.9
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphoma
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.10
Adverse Events of Special Interest of CTCAE Grade >=3 - Hepatic disorder
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	4 (1.2)
Unstratified Analysis		
Odds Ratio	0.109	
95% CI	0.006, 2.024	
p-value	0.1369	
Relative Risk	0.110	
95% CI	0.006, 2.032	
p-value	0.1379	
Risk Difference	-0.012	
95% CI	-0.023, -0.000	
p-value	0.0442	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.11
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.12
Adverse Events of Special Interest of CTCAE Grade >=3 - Anemia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.13
Adverse Events of Special Interest of CTCAE Grade >=3 - Neutropenia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	2 (0.6)	1 (0.3)
Unstratified Analysis		
Odds Ratio	1.983	
95% CI	0.179, 21.967	
p-value	0.5770	
Relative Risk	1.977	
95% CI	0.180, 21.702	
p-value	0.5771	
Risk Difference	0.003	
95% CI	-0.007, 0.013	
p-value	0.5688	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.14
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphopenia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.15
Adverse Events of Special Interest of CTCAE Grade >=3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	7 (2.0)	6 (1.7)
Unstratified Analysis		
Odds Ratio	1.156	
95% CI	0.385, 3.477	
p-value	0.7958	
Relative Risk	1.153	
95% CI	0.392, 3.397	
p-value	0.7958	
Risk Difference	0.003	
95% CI	-0.018, 0.023	
p-value	0.7956	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.16
Adverse Events of Special Interest of CTCAE Grade >=3 - Renal dysfunction
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Unstratified Analysis		
Odds Ratio	2.974	
95% CI	0.121, 73.260	
p-value	0.5049	
Relative Risk	2.966	
95% CI	0.121, 72.547	
p-value	0.5051	
Risk Difference	0.003	
95% CI	-0.003, 0.008	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.17
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.12.18
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.1
Adverse Events of Special Interest of CTCAE Grade <3 - Serious Infection
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.2
Adverse Events of Special Interest of CTCAE Grade <3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	3 (0.9)	0 (0.0)
Unstratified Analysis		
Odds Ratio	6.980	
95% CI	0.359, 135.633	
p-value	0.1993	
Relative Risk	6.920	
95% CI	0.359, 133.464	
p-value	0.2002	
Risk Difference	0.009	
95% CI	-0.001, 0.018	
p-value	0.0819	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.3
Adverse Events of Special Interest of CTCAE Grade <3 - Herpes zoster
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	12 (3.4)	4 (1.2)
Unstratified Analysis		
Odds Ratio	3.036	
95% CI	0.969, 9.507	
p-value	0.0566	
Relative Risk	2.966	
95% CI	0.966, 9.105	
p-value	0.0575	
Risk Difference	0.023	
95% CI	0.001, 0.045	
p-value	0.0443	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.4
Adverse Events of Special Interest of CTCAE Grade <3 - Active tuberculosis
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.5
Adverse Events of Special Interest of CTCAE Grade <3 - Possible malignancy
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Unstratified Analysis		
Odds Ratio	0.329	
95% CI	0.013, 8.093	
p-value	0.4960	
Relative Risk	0.330	
95% CI	0.013, 8.061	
p-value	0.4962	
Risk Difference	-0.003	
95% CI	-0.009, 0.003	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.6
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Unstratified Analysis		
Odds Ratio	0.329	
95% CI	0.013, 8.093	
p-value	0.4960	
Relative Risk	0.330	
95% CI	0.013, 8.061	
p-value	0.4962	
Risk Difference	-0.003	
95% CI	-0.009, 0.003	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.7
Adverse Events of Special Interest of CTCAE Grade <3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Unstratified Analysis		
Odds Ratio	0.329	
95% CI	0.013, 8.093	
p-value	0.4960	
Relative Risk	0.330	
95% CI	0.013, 8.061	
p-value	0.4962	
Risk Difference	-0.003	
95% CI	-0.009, 0.003	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.8
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy other than NMSC
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.9
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphoma
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.10
Adverse Events of Special Interest of CTCAE Grade <3 - Hepatic disorder
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	12 (3.4)	3 (0.9)
Unstratified Analysis		
Odds Ratio	4.060	
95% CI	1.135, 14.515	
p-value	0.0311	
Relative Risk	3.954	
95% CI	1.126, 13.889	
p-value	0.0320	
Risk Difference	0.026	
95% CI	0.004, 0.047	
p-value	0.0191	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Upadacitinib (M16-046) - (Final Datacut) Final
Table 3.1.13.10.1
Adverse Events of Special Interest of CTCAE Grade <3 - Hepatic disorder - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.9953
< 40 years	8/228 (3.5)	2/226 (0.9)	3.965	(0.851, 18.467)	0.0793	
>= 40 years	4/120 (3.3)	1/118 (0.8)	3.933	(0.446, 34.675)	0.2175	
Geographic regions						0.0399
US/PR/Canada	7/140 (5.0)	0/131 (0.0)	14.043	(0.810, 243.458)	0.0695	
Other	5/208 (2.4)	3/213 (1.4)	1.707	(0.413, 7.051)	0.4601	
Baseline EASI						0.4977
< Median (26.4)	6/165 (3.6)	1/180 (0.6)	6.545	(0.796, 53.796)	0.0804	
>= Median (26.4)	6/183 (3.3)	2/164 (1.2)	2.689	(0.550, 13.136)	0.2217	
Baseline vIGA-AD						0.4271
3 (Moderate)	5/174 (2.9)	2/171 (1.2)	2.457	(0.483, 12.492)	0.2786	
4 (Severe)	7/174 (4.0)	1/173 (0.6)	6.960	(0.865, 55.971)	0.0681	
Sex						0.1124
Female	5/165 (3.0)	0/150 (0.0)	10.006	(0.558, 179.440)	0.1179	
Male	7/183 (3.8)	3/194 (1.5)	2.474	(0.649, 9.422)	0.1844	
BMI						0.5851
< 25 kg/m2	4/161 (2.5)	2/169 (1.2)	2.099	(0.390, 11.305)	0.3879	
>= 25 - < 30 kg/m2	3/ 93 (3.2)	0/110 (0.0)	8.266	(0.432, 157.996)	0.1606	
>= 30 kg/m2	5/ 93 (5.4)	1/ 65 (1.5)	3.495	(0.418, 29.217)	0.2482	
Race						NE
White	6/235 (2.6)	3/244 (1.2)	2.077	(0.525, 8.207)	0.2973	
Asian	3/ 77 (3.9)	0/ 78 (0.0)	7.090	(0.372, 135.000)	0.1926	
Other	3/ 36 (8.3)	0/ 22 (0.0)	4.351	(0.235, 80.448)	0.3232	
Baseline hsCRP						0.4113
< Median (1.745)	4/161 (2.5)	2/185 (1.1)	2.298	(0.427, 12.382)	0.3329	
>= Median(1.745)	8/187 (4.3)	1/159 (0.6)	6.802	(0.860, 53.802)	0.0692	
Previous systemic therapy						0.4170
With	5/180 (2.8)	2/175 (1.1)	2.431	(0.478, 12.363)	0.2845	
Without	7/168 (4.2)	1/169 (0.6)	7.042	(0.876, 56.612)	0.0665	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.13.11
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.12
Adverse Events of Special Interest of CTCAE Grade <3 - Anemia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	8 (2.3)	1 (0.3)
Unstratified Analysis		
Odds Ratio	8.071	
95% CI	1.004, 64.877	
p-value	0.0496	
Relative Risk	7.908	
95% CI	0.994, 62.890	
p-value	0.0506	
Risk Difference	0.020	
95% CI	0.003, 0.037	
p-value	0.0187	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.13
Adverse Events of Special Interest of CTCAE Grade <3 - Neutropenia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	4 (1.1)	1 (0.3)
Unstratified Analysis		
Odds Ratio	3.988	
95% CI	0.444, 35.866	
p-value	0.2170	
Relative Risk	3.954	
95% CI	0.444, 35.197	
p-value	0.2178	
Risk Difference	0.009	
95% CI	-0.004, 0.021	
p-value	0.1803	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.14
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphopenia
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	2 (0.6)	0 (0.0)
Unstratified Analysis		
Odds Ratio	4.971	
95% CI	0.238, 103.925	
p-value	0.3012	
Relative Risk	4.943	
95% CI	0.238, 102.578	
p-value	0.3018	
Risk Difference	0.006	
95% CI	-0.002, 0.014	
p-value	0.1561	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.15
Adverse Events of Special Interest of CTCAE Grade <3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	19 (5.5)	6 (1.7)
Unstratified Analysis		
Odds Ratio	3.253	
95% CI	1.283, 8.248	
p-value	0.0129	
Relative Risk	3.130	
95% CI	1.265, 7.743	
p-value	0.0135	
Risk Difference	0.037	
95% CI	0.010, 0.065	
p-value	0.0083	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.15.1
Adverse Events of Special Interest of CTCAE Grade <3 - Creatine phosphokinase (CPK) elevation - Subgroup analysis
(Safety Analysis Set)

Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
Age						0.4612
< 40 years	13/228 (5.7)	5/226 (2.2)	2.577	(0.934, 7.110)	0.0675	
>= 40 years	6/120 (5.0)	1/118 (0.8)	5.900	(0.721, 48.262)	0.0979	
Geographic regions						0.1852
US/PR/Canada	9/140 (6.4)	1/131 (0.8)	8.421	(1.082, 65.561)	0.0418	
Other	10/208 (4.8)	5/213 (2.3)	2.048	(0.712, 5.890)	0.1835	
Baseline EASI						0.0614
< Median (26.4)	7/165 (4.2)	5/180 (2.8)	1.527	(0.494, 4.719)	0.4618	
>= Median (26.4)	12/183 (6.6)	1/164 (0.6)	10.754	(1.414, 81.807)	0.0218	
Baseline vIGA-AD						0.0001
3 (Moderate)	4/174 (2.3)	6/171 (3.5)	0.655	(0.188, 2.281)	0.5064	
4 (Severe)	15/174 (8.6)	0/173 (0.0)	30.823	(1.859, 511.112)	0.0167	
Sex						0.4536
Female	4/165 (2.4)	2/150 (1.3)	1.818	(0.338, 9.784)	0.4863	
Male	15/183 (8.2)	4/194 (2.1)	3.975	(1.344, 11.757)	0.0126	
BMI						0.1142
< 25 kg/m2	5/161 (3.1)	5/169 (3.0)	1.050	(0.310, 3.558)	0.9379	
>= 25 - < 30 kg/m2	9/ 93 (9.7)	0/110 (0.0)	22.436	(1.323, 380.387)	0.0312	
>= 30 kg/m2	5/ 93 (5.4)	1/ 65 (1.5)	3.495	(0.418, 29.217)	0.2482	
Race						0.6352
White	10/235 (4.3)	4/244 (1.6)	2.596	(0.826, 8.162)	0.1027	
Asian	4/ 77 (5.2)	0/ 78 (0.0)	9.115	(0.499, 166.485)	0.1359	
Other	5/ 36 (13.9)	2/ 22 (9.1)	1.528	(0.324, 7.210)	0.5924	
Baseline hsCRP						0.0526
< Median (1.745)	12/161 (7.5)	6/185 (3.2)	2.298	(0.883, 5.984)	0.0883	
>= Median(1.745)	7/187 (3.7)	0/159 (0.0)	12.766	(0.735, 221.788)	0.0804	
Previous systemic therapy						0.9386
With	10/180 (5.6)	3/175 (1.7)	3.241	(0.907, 11.578)	0.0703	
Without	9/168 (5.4)	3/169 (1.8)	3.018	(0.831, 10.953)	0.0931	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.1.13.16
Adverse Events of Special Interest of CTCAE Grade <3 - Renal dysfunction
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Unstratified Analysis		
Odds Ratio	0.329	
95% CI	0.013, 8.093	
p-value	0.4960	
Relative Risk	0.330	
95% CI	0.013, 8.061	
p-value	0.4962	
Risk Difference	-0.003	
95% CI	-0.009, 0.003	
p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.17
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.1.13.18
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

	Upadacitinib (N=348)	Dupilumab (N=344)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Unstratified Analysis		
Odds Ratio	NE	
95% CI	NE, NE	
p-value	NE	
Relative Risk	NE	
95% CI	NE, NE	
p-value	NE	
Risk Difference	NE	
95% CI	NE, NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.2.2
Incidence of Adverse Events leading to discontinuation of study drug by SOC and PT
(Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	Upadacitinib (N=348) n (%)	Dupilumab (N=344) n (%)
Skin and subcutaneous tissue disorders	2 (0.6)	2 (0.6)
Dermatitis atopic	1 (0.3)	0 (0.0)
Eczema	1 (0.3)	0 (0.0)
Erythema multiforme	0 (0.0)	1 (0.3)
Urticaria	0 (0.0)	1 (0.3)
Investigations	3 (0.9)	0 (0.0)
Alanine aminotransferase increased	2 (0.6)	0 (0.0)
Aspartate aminotransferase increased	1 (0.3)	0 (0.0)
Haemoglobin decreased	1 (0.3)	0 (0.0)
General disorders and administration site conditions	1 (0.3)	1 (0.3)
Fatigue	1 (0.3)	1 (0.3)
Infections and infestations	2 (0.6)	0 (0.0)
Influenza	2 (0.6)	0 (0.0)
Beta haemolytic streptococcal infection	1 (0.3)	0 (0.0)
Pneumonia	1 (0.3)	0 (0.0)
Staphylococcal infection	1 (0.3)	0 (0.0)
Blood and lymphatic system disorders	1 (0.3)	0 (0.0)
Lymphopenia	1 (0.3)	0 (0.0)
Neutropenia	1 (0.3)	0 (0.0)
Immune system disorders	0 (0.0)	1 (0.3)
Type I hypersensitivity	0 (0.0)	1 (0.3)
Musculoskeletal and connective tissue disorders	0 (0.0)	1 (0.3)
Arthralgia	0 (0.0)	1 (0.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.3)	0 (0.0)
Invasive ductal breast carcinoma	1 (0.3)	0 (0.0)
Surgical and medical procedures	1 (0.3)	0 (0.0)
Abortion induced	1 (0.3)	0 (0.0)

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.1 coding dictionary applied.
N: Number of subjects, n: Number of subjects with event

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	17 (4.9)	4 (1.2)
	Unstratified Analysis		
	Odds Ratio	4.366	
	95% CI	1.454, 13.110	
	p-value	0.0086	
	Relative Risk	4.201	
	95% CI	1.428, 12.358	
	p-value	0.0091	
	Risk Difference	0.037	
	95% CI	0.012, 0.063	
	p-value	0.0040	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Eye disorders	Number of subjects with events, n (%)	26 (7.5)	49 (14.2)
	Unstratified Analysis		
	Odds Ratio	0.486	
	95% CI	0.295, 0.802	
	p-value	0.0048	
	Relative Risk	0.525	
	95% CI	0.334, 0.824	
	p-value	0.0051	
	Risk Difference	-0.068	
	95% CI	-0.114, -0.022	
	p-value	0.0040	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Eye disorders - PT:Dry eye	Number of subjects with events, n (%)	5 (1.4)	12 (3.5)
	Unstratified Analysis		
	Odds Ratio	0.403	
	95% CI	0.141, 1.157	
	p-value	0.0913	
	Relative Risk	0.412	
	95% CI	0.147, 1.157	
	p-value	0.0922	
	Risk Difference	-0.021	
	95% CI	-0.044, 0.003	
	p-value	0.0814	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	55 (15.8)	49 (14.2)
	Unstratified Analysis		
	Odds Ratio	1.130	
	95% CI	0.744, 1.716	
	p-value	0.5659	
	Relative Risk	1.110	
	95% CI	0.778, 1.582	
	p-value	0.5660	
	Risk Difference	0.016	
	95% CI	-0.038, 0.069	
	p-value	0.5656	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Gastrointestinal disorders - PT:Diarrhoea	Number of subjects with events, n (%)	16 (4.6)	9 (2.6)
	Unstratified Analysis		
	Odds Ratio	1.794	
	95% CI	0.782, 4.116	
	p-value	0.1679	
	Relative Risk	1.757	
	95% CI	0.787, 3.923	
	p-value	0.1687	
	Risk Difference	0.020	
	95% CI	-0.008, 0.048	
	p-value	0.1613	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Gastrointestinal disorders - PT:Nausea	Number of subjects with events, n (%)	10 (2.9)	14 (4.1)
	Unstratified Analysis		
	Odds Ratio	0.697	
	95% CI	0.305, 1.592	
	p-value	0.3922	
	Relative Risk	0.706	
	95% CI	0.318, 1.568	
	p-value	0.3925	
	Risk Difference	-0.012	
	95% CI	-0.039, 0.015	
	p-value	0.3901	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	31 (8.9)	22 (6.4)
	Unstratified Analysis		
	Odds Ratio	1.431	
	95% CI	0.811, 2.526	
	p-value	0.2159	
	Relative Risk	1.393	
	95% CI	0.823, 2.356	
	p-value	0.2166	
	Risk Difference	0.025	
	95% CI	-0.014, 0.065	
	p-value	0.2131	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Infections and infestations	Number of subjects with events, n (%)	161 (46.3)	133 (38.7)
	Unstratified Analysis		
	Odds Ratio	1.366	
	95% CI	1.009, 1.848	
	p-value	0.0433	
	Relative Risk	1.197	
	95% CI	1.005, 1.425	
	p-value	0.0441	
	Risk Difference	0.076	
	95% CI	0.003, 0.149	
	p-value	0.0425	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Infections and infestations - PT:Conjunctivitis	Number of subjects with events, n (%)	5 (1.4)	35 (10.2)
	Unstratified Analysis		
	Odds Ratio	0.129	
	95% CI	0.050, 0.333	
	p-value	<.0001	
	Relative Risk	0.141	
	95% CI	0.056, 0.356	
	p-value	<.0001	
	Risk Difference	-0.087	
	95% CI	-0.122, -0.053	
	p-value	<.0001	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Infections and infestations - PT:Folliculitis	Number of subjects with events, n (%)	22 (6.3)	4 (1.2)
	Unstratified Analysis		
	Odds Ratio	5.736	
	95% CI	1.956, 16.826	
	p-value	0.0015	
	Relative Risk	5.437	
	95% CI	1.893, 15.612	
	p-value	0.0017	
	Risk Difference	0.052	
	95% CI	0.024, 0.080	
	p-value	0.0003	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Infections and infestations - PT:Herpes simplex	Number of subjects with events, n (%)	11 (3.2)	7 (2.0)
	Unstratified Analysis		
	Odds Ratio	1.571	
	95% CI	0.602, 4.102	
	p-value	0.3559	
	Relative Risk	1.553	
	95% CI	0.609, 3.960	
	p-value	0.3563	
	Risk Difference	0.011	
	95% CI	-0.012, 0.035	
	p-value	0.3512	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Infections and infestations - PT:Nasopharyngitis	Number of subjects with events, n (%)	23 (6.6)	27 (7.8)
	Unstratified Analysis		
	Odds Ratio	0.831	
	95% CI	0.466, 1.480	
	p-value	0.5293	
	Relative Risk	0.842	
	95% CI	0.493, 1.439	
	p-value	0.5295	
	Risk Difference	-0.012	
	95% CI	-0.051, 0.026	
	p-value	0.5289	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Infections and infestations - PT:Oral herpes	Number of subjects with events, n (%)	17 (4.9)	9 (2.6)
	Unstratified Analysis		
	Odds Ratio	1.912	
	95% CI	0.840, 4.350	
	p-value	0.1224	
	Relative Risk	1.867	
	95% CI	0.844, 4.131	
	p-value	0.1233	
	Risk Difference	0.023	
	95% CI	-0.006, 0.051	
	p-value	0.1153	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Infections and infestations - PT:Upper respiratory tract infection	Number of subjects with events, n (%)	26 (7.5)	17 (4.9)
	Unstratified Analysis		
	Odds Ratio	1.553	
	95% CI	0.827, 2.917	
	p-value	0.1710	
	Relative Risk	1.512	
	95% CI	0.836, 2.735	
	p-value	0.1718	
	Risk Difference	0.025	
	95% CI	-0.011, 0.061	
	p-value	0.1671	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Infections and infestations - PT:Urinary tract infection	Number of subjects with events, n (%)	19 (5.5)	15 (4.4)
	Unstratified Analysis		
	Odds Ratio	1.267	
	95% CI	0.633, 2.535	
	p-value	0.5044	
	Relative Risk	1.252	
	95% CI	0.647, 2.423	
	p-value	0.5046	
	Risk Difference	0.011	
	95% CI	-0.021, 0.043	
	p-value	0.5031	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	23 (6.6)	30 (8.7)
	Unstratified Analysis		
	Odds Ratio	0.741	
	95% CI	0.421, 1.303	
	p-value	0.2977	
	Relative Risk	0.758	
	95% CI	0.449, 1.278	
	p-value	0.2982	
	Risk Difference	-0.021	
	95% CI	-0.061, 0.019	
	p-value	0.2963	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Investigations	Number of subjects with events, n (%)	48 (13.8)	32 (9.3)
	Unstratified Analysis		
	Odds Ratio	1.560	
	95% CI	0.971, 2.507	
	p-value	0.0663	
	Relative Risk	1.483	
	95% CI	0.973, 2.261	
	p-value	0.0672	
	Risk Difference	0.045	
	95% CI	-0.003, 0.092	
	p-value	0.0638	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Investigations - PT:Blood creatine phosphokinase increased	Number of subjects with events, n (%)	26 (7.5)	11 (3.2)
	Unstratified Analysis		
	Odds Ratio	2.444	
	95% CI	1.188, 5.029	
	p-value	0.0152	
	Relative Risk	2.336	
	95% CI	1.173, 4.654	
	p-value	0.0158	
	Risk Difference	0.043	
	95% CI	0.009, 0.076	
	p-value	0.0119	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	15 (4.3)	6 (1.7)
	Unstratified Analysis		
	Odds Ratio	2.538	
	95% CI	0.973, 6.619	
	p-value	0.0570	
	Relative Risk	2.471	
	95% CI	0.970, 6.295	
	p-value	0.0579	
	Risk Difference	0.026	
	95% CI	0.000, 0.051	
	p-value	0.0479	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	24 (6.9)	25 (7.3)
	Unstratified Analysis		
	Odds Ratio	0.945	
	95% CI	0.529, 1.690	
	p-value	0.8492	
	Relative Risk	0.949	
	95% CI	0.553, 1.628	
	p-value	0.8492	
	Risk Difference	-0.004	
	95% CI	-0.042, 0.035	
	p-value	0.8492	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Nervous system disorders	Number of subjects with events, n (%)	28 (8.0)	39 (11.3)
	Unstratified Analysis		
	Odds Ratio	0.684	
	95% CI	0.411, 1.140	
	p-value	0.1450	
	Relative Risk	0.710	
	95% CI	0.447, 1.127	
	p-value	0.1458	
	Risk Difference	-0.033	
	95% CI	-0.077, 0.011	
	p-value	0.1430	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Nervous system disorders - PT:Headache	Number of subjects with events, n (%)	17 (4.9)	24 (7.0)
	Unstratified Analysis		
	Odds Ratio	0.685	
	95% CI	0.361, 1.299	
	p-value	0.2463	
	Relative Risk	0.700	
	95% CI	0.383, 1.280	
	p-value	0.2468	
	Risk Difference	-0.021	
	95% CI	-0.056, 0.014	
	p-value	0.2439	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	13 (3.7)	10 (2.9)
	Unstratified Analysis		
	Odds Ratio	1.296	
	95% CI	0.561, 2.997	
	p-value	0.5442	
	Relative Risk	1.285	
	95% CI	0.571, 2.891	
	p-value	0.5443	
	Risk Difference	0.008	
	95% CI	-0.018, 0.035	
	p-value	0.5428	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	25 (7.2)	20 (5.8)
	Unstratified Analysis		
	Odds Ratio	1.254	
	95% CI	0.683, 2.303	
	p-value	0.4657	
	Relative Risk	1.236	
	95% CI	0.700, 2.182	
	p-value	0.4660	
	Risk Difference	0.014	
	95% CI	-0.023, 0.050	
	p-value	0.4645	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	121 (34.8)	79 (23.0)
	Unstratified Analysis		
	Odds Ratio	1.788	
	95% CI	1.280, 2.498	
	p-value	0.0007	
	Relative Risk	1.514	
	95% CI	1.190, 1.927	
	p-value	0.0007	
	Risk Difference	0.118	
	95% CI	0.051, 0.185	
	p-value	0.0005	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Skin and subcutaneous tissue disorders - PT:Acne	Number of subjects with events, n (%)	64 (18.4)	11 (3.2)
	Unstratified Analysis		
	Odds Ratio	6.822	
	95% CI	3.529, 13.186	
	p-value	<.0001	
	Relative Risk	5.751	
	95% CI	3.087, 10.714	
	p-value	<.0001	
	Risk Difference	0.152	
	95% CI	0.107, 0.197	
	p-value	<.0001	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Skin and subcutaneous tissue disorders - PT:Dermatitis atopic	Number of subjects with events, n (%)	37 (10.6)	32 (9.3)
	Unstratified Analysis		
	Odds Ratio	1.160	
	95% CI	0.705, 1.910	
	p-value	0.5596	
	Relative Risk	1.143	
	95% CI	0.729, 1.791	
	p-value	0.5598	
	Risk Difference	0.013	
	95% CI	-0.031, 0.058	
	p-value	0.5591	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Vascular disorders	Number of subjects with events, n (%)	16 (4.6)	12 (3.5)
	Unstratified Analysis		
	Odds Ratio	1.333	
	95% CI	0.621, 2.862	
	p-value	0.4604	
	Relative Risk	1.318	
	95% CI	0.633, 2.745	
	p-value	0.4606	
	Risk Difference	0.011	
	95% CI	-0.018, 0.040	
	p-value	0.4585	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Vascular disorders - PT:Hypertension	Number of subjects with events, n (%)	13 (3.7)	6 (1.7)
	Unstratified Analysis		
	Odds Ratio	2.186	
	95% CI	0.821, 5.819	
	p-value	0.1174	
	Relative Risk	2.142	
	95% CI	0.824, 5.570	
	p-value	0.1183	
	Risk Difference	0.020	
	95% CI	-0.004, 0.044	
	p-value	0.1076	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.1.1

Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

(Safety Analysis Set)

SOC/PT	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders	Age						0.8630
	< 40 years	12/228 (5.3)	3/226 (1.3)	3.965	(1.134, 13.862)	0.0310	
	>= 40 years	5/120 (4.2)	1/118 (0.8)	4.917	(0.583, 41.454)	0.1432	
	Geographic regions						0.5323
	US/PR/Canada	6/140 (4.3)	2/131 (1.5)	2.807	(0.577, 13.662)	0.2011	
	Other	11/208 (5.3)	2/213 (0.9)	5.632	(1.264, 25.103)	0.0234	
	Baseline EASI						0.7127
	< Median (26.4)	6/165 (3.6)	2/180 (1.1)	3.273	(0.670, 15.989)	0.1429	
	>= Median (26.4)	11/183 (6.0)	2/164 (1.2)	4.929	(1.109, 21.910)	0.0361	
	Baseline vIGA-AD						0.7550
	3 (Moderate)	10/174 (5.7)	2/171 (1.2)	4.914	(1.093, 22.098)	0.0379	
	4 (Severe)	7/174 (4.0)	2/173 (1.2)	3.480	(0.733, 16.516)	0.1166	
	Sex						0.3348
	Female	9/165 (5.5)	3/150 (2.0)	2.727	(0.752, 9.886)	0.1268	
	Male	8/183 (4.4)	1/194 (0.5)	8.481	(1.071, 67.144)	0.0429	
	BMI						0.1792
	< 25 kg/m2	8/161 (5.0)	3/169 (1.8)	2.799	(0.756, 10.366)	0.1233	
	>= 25 - < 30 kg/m2	3/ 93 (3.2)	1/110 (0.9)	3.548	(0.375, 33.541)	0.2691	
	>= 30 kg/m2	6/ 93 (6.5)	0/ 65 (0.0)	9.128	(0.523, 159.250)	0.1296	
	Race						NE
	White	10/235 (4.3)	4/244 (1.6)	2.596	(0.826, 8.162)	0.1027	
	Asian	3/ 77 (3.9)	0/ 78 (0.0)	7.090	(0.372, 135.000)	0.1926	
	Other	4/ 36 (11.1)	0/ 22 (0.0)	5.595	(0.316, 99.168)	0.2405	
	Baseline hsCRP						0.4176
	< Median (1.745)	11/161 (6.8)	2/185 (1.1)	6.320	(1.422, 28.091)	0.0154	
	>= Median(1.745)	6/187 (3.2)	2/159 (1.3)	2.551	(0.522, 12.462)	0.2473	
	Previous systemic therapy						0.0071
	With	6/180 (3.3)	4/175 (2.3)	1.458	(0.419, 5.080)	0.5535	
	Without	11/168 (6.5)	0/169 (0.0)	23.136	(1.374, 389.476)	0.0292	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.3.1.1

Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

(Safety Analysis Set)

SOC/PT	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)		p-Value	Interaction p-Value
SOC: Eye disorders	Age							0.8698
	< 40 years	17/228 (7.5)	33/226 (14.6)	0.511	(0.293,	0.890)	0.0177	
	>= 40 years	9/120 (7.5)	16/118 (13.6)	0.553	(0.255,	1.202)	0.1348	
	Geographic regions							0.3384
	US/PR/Canada	7/140 (5.0)	8/131 (6.1)	0.819	(0.305,	2.195)	0.6910	
	Other	19/208 (9.1)	41/213 (19.2)	0.475	(0.285,	0.790)	0.0041	
	Baseline EASI							0.1239
	< Median (26.4)	15/165 (9.1)	22/180 (12.2)	0.744	(0.400,	1.385)	0.3505	
	>= Median (26.4)	11/183 (6.0)	27/164 (16.5)	0.365	(0.187,	0.713)	0.0031	
	Baseline vIGA-AD							0.0216
	3 (Moderate)	17/174 (9.8)	19/171 (11.1)	0.879	(0.473,	1.634)	0.6840	
	4 (Severe)	9/174 (5.2)	30/173 (17.3)	0.298	(0.146,	0.609)	0.0009	
	Sex							0.7244
	Female	10/165 (6.1)	19/150 (12.7)	0.478	(0.230,	0.996)	0.0487	
	Male	16/183 (8.7)	30/194 (15.5)	0.565	(0.319,	1.002)	0.0508	
	BMI							0.4175
	< 25 kg/m2	15/161 (9.3)	32/169 (18.9)	0.492	(0.277,	0.874)	0.0155	
	>= 25 - < 30 kg/m2	5/ 93 (5.4)	12/110 (10.9)	0.493	(0.180,	1.348)	0.1681	
	>= 30 kg/m2	6/ 93 (6.5)	5/ 65 (7.7)	0.839	(0.267,	2.632)	0.7631	
	Race							0.0759
	White	17/235 (7.2)	31/244 (12.7)	0.569	(0.324,	1.001)	0.0502	
	Asian	8/ 77 (10.4)	11/ 78 (14.1)	0.737	(0.313,	1.732)	0.4834	
	Other	1/ 36 (2.8)	7/ 22 (31.8)	0.087	(0.011,	0.663)	0.0184	
	Baseline hsCRP							0.2446
	< Median (1.745)	18/161 (11.2)	31/185 (16.8)	0.667	(0.388,	1.146)	0.1427	
	>= Median(1.745)	8/187 (4.3)	18/159 (11.3)	0.378	(0.169,	0.846)	0.0179	
	Previous systemic therapy							0.9498
	With	17/180 (9.4)	32/175 (18.3)	0.516	(0.298,	0.895)	0.0186	
	Without	9/168 (5.4)	17/169 (10.1)	0.533	(0.244,	1.161)	0.1130	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.3.1.1

Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

(Safety Analysis Set)

SOC/PT	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)		p-Value	Interaction p-Value
SOC: Infections and infestations	Age							0.0398
	< 40 years	102/228 (44.7)	96/226 (42.5)	1.053	(0.854,	1.298)	0.6276	
	>= 40 years	59/120 (49.2)	37/118 (31.4)	1.568	(1.135,	2.166)	0.0064	
	Geographic regions							0.6703
	US/PR/Canada	52/140 (37.1)	38/131 (29.0)	1.280	(0.908,	1.806)	0.1587	
	Other	109/208 (52.4)	95/213 (44.6)	1.175	(0.964,	1.432)	0.1104	
	Baseline EASI							0.5384
	< Median (26.4)	74/165 (44.8)	64/180 (35.6)	1.261	(0.973,	1.635)	0.0794	
	>= Median (26.4)	87/183 (47.5)	69/164 (42.1)	1.130	(0.893,	1.430)	0.3090	
	Baseline vIGA-AD							0.9398
	3 (Moderate)	70/174 (40.2)	57/171 (33.3)	1.207	(0.913,	1.595)	0.1862	
	4 (Severe)	91/174 (52.3)	76/173 (43.9)	1.190	(0.955,	1.484)	0.1206	
	Sex							0.6095
	Female	80/165 (48.5)	64/150 (42.7)	1.136	(0.891,	1.449)	0.3029	
	Male	81/183 (44.3)	69/194 (35.6)	1.244	(0.970,	1.597)	0.0859	
	BMI							0.5975
	< 25 kg/m2	80/161 (49.7)	62/169 (36.7)	1.354	(1.053,	1.742)	0.0182	
	>= 25 - < 30 kg/m2	40/ 93 (43.0)	50/110 (45.5)	0.946	(0.693,	1.291)	0.7275	
	>= 30 kg/m2	41/ 93 (44.1)	21/ 65 (32.3)	1.365	(0.897,	2.076)	0.1467	
	Race							0.9081
	White	108/235 (46.0)	96/244 (39.3)	1.168	(0.948,	1.439)	0.1443	
	Asian	40/ 77 (51.9)	29/ 78 (37.2)	1.397	(0.975,	2.002)	0.0683	
	Other	13/ 36 (36.1)	8/ 22 (36.4)	0.993	(0.492,	2.006)	0.9845	
	Baseline hsCRP							0.1541
	< Median (1.745)	78/161 (48.4)	66/185 (35.7)	1.358	(1.057,	1.745)	0.0167	
	>= Median(1.745)	83/187 (44.4)	67/159 (42.1)	1.053	(0.826,	1.343)	0.6749	
	Previous systemic therapy							0.0777
	With	88/180 (48.9)	82/175 (46.9)	1.043	(0.840,	1.297)	0.7018	
	Without	73/168 (43.5)	51/169 (30.2)	1.440	(1.081,	1.918)	0.0128	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.3.1.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
(Safety Analysis Set)

SOC/PT	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations - PT:Conjunctivitis	Age						0.4269
	< 40 years	3/228 (1.3)	27/226 (11.9)	0.110	(0.034, 0.358)	0.0002	
	>= 40 years	2/120 (1.7)	8/118 (6.8)	0.246	(0.053, 1.134)	0.0720	
	Geographic regions						0.6167
	US/PR/Canada	1/140 (0.7)	10/131 (7.6)	0.094	(0.012, 0.721)	0.0230	
	Other	4/208 (1.9)	25/213 (11.7)	0.164	(0.058, 0.463)	0.0006	
	Baseline EASI						0.9349
	< Median (26.4)	2/165 (1.2)	15/180 (8.3)	0.145	(0.034, 0.626)	0.0097	
	>= Median (26.4)	3/183 (1.6)	20/164 (12.2)	0.134	(0.041, 0.444)	0.0010	
	Baseline vIGA-AD						0.2744
	3 (Moderate)	3/174 (1.7)	12/171 (7.0)	0.246	(0.071, 0.855)	0.0274	
	4 (Severe)	2/174 (1.1)	23/173 (13.3)	0.086	(0.021, 0.361)	0.0008	
	Sex						0.3449
	Female	3/165 (1.8)	12/150 (8.0)	0.227	(0.065, 0.790)	0.0197	
	Male	2/183 (1.1)	23/194 (11.9)	0.092	(0.022, 0.385)	0.0011	
	BMI						0.6813
	< 25 kg/m2	3/161 (1.9)	15/169 (8.9)	0.210	(0.062, 0.712)	0.0122	
	>= 25 - < 30 kg/m2	1/ 93 (1.1)	17/110 (15.5)	0.070	(0.009, 0.513)	0.0089	
	>= 30 kg/m2	1/ 93 (1.1)	3/ 65 (4.6)	0.233	(0.025, 2.190)	0.2026	
	Race						0.5146
	White	4/235 (1.7)	27/244 (11.1)	0.154	(0.055, 0.433)	0.0004	
	Asian	1/ 77 (1.3)	6/ 78 (7.7)	0.169	(0.021, 1.370)	0.0958	
	Other	0/ 36 (0.0)	2/ 22 (9.1)	0.124	(0.006, 2.476)	0.1719	
	Baseline hsCRP						0.5932
	< Median (1.745)	2/161 (1.2)	21/185 (11.4)	0.109	(0.026, 0.460)	0.0025	
	>= Median(1.745)	3/187 (1.6)	14/159 (8.8)	0.182	(0.053, 0.623)	0.0066	
	Previous systemic therapy						0.8732
	With	3/180 (1.7)	22/175 (12.6)	0.133	(0.040, 0.435)	0.0009	
	Without	2/168 (1.2)	13/169 (7.7)	0.155	(0.035, 0.675)	0.0131	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.3.1.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
(Safety Analysis Set)

SOC/PT	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations - PT:Folliculitis	Age						0.0703
	< 40 years	14/228 (6.1)	4/226 (1.8)	3.469	(1.160, 10.379)	0.0261	
	>= 40 years	8/120 (6.7)	0/118 (0.0)	16.719	(0.976, 286.422)	0.0520	
	Geographic regions						0.3706
	US/PR/Canada	2/140 (1.4)	1/131 (0.8)	1.871	(0.172, 20.395)	0.6071	
	Other	20/208 (9.6)	3/213 (1.4)	6.827	(2.060, 22.629)	0.0017	
	Baseline EASI						0.8741
	< Median (26.4)	9/165 (5.5)	2/180 (1.1)	4.909	(1.076, 22.390)	0.0399	
	>= Median (26.4)	13/183 (7.1)	2/164 (1.2)	5.825	(1.334, 25.429)	0.0191	
	Baseline vIGA-AD						0.2586
	3 (Moderate)	10/174 (5.7)	3/171 (1.8)	3.276	(0.917, 11.698)	0.0677	
	4 (Severe)	12/174 (6.9)	1/173 (0.6)	11.931	(1.568, 90.763)	0.0166	
	Sex						0.7480
	Female	8/165 (4.8)	1/150 (0.7)	7.273	(0.920, 57.466)	0.0599	
	Male	14/183 (7.7)	3/194 (1.5)	4.947	(1.445, 16.934)	0.0109	
	BMI						0.1986
	< 25 kg/m2	11/161 (6.8)	1/169 (0.6)	11.547	(1.508, 88.420)	0.0185	
	>= 25 - < 30 kg/m2	10/ 93 (10.8)	2/110 (1.8)	5.914	(1.329, 26.316)	0.0196	
	>= 30 kg/m2	1/ 93 (1.1)	1/ 65 (1.5)	0.699	(0.045, 10.973)	0.7987	
	Race						0.5146
	White	11/235 (4.7)	0/244 (0.0)	23.877	(1.415, 402.903)	0.0278	
	Asian	10/ 77 (13.0)	4/ 78 (5.1)	2.532	(0.830, 7.730)	0.1027	
	Other	1/ 36 (2.8)	0/ 22 (0.0)	1.865	(0.079, 43.869)	0.6989	
	Baseline hsCRP						0.7186
	< Median (1.745)	13/161 (8.1)	3/185 (1.6)	4.979	(1.445, 17.163)	0.0110	
	>= Median(1.745)	9/187 (4.8)	1/159 (0.6)	7.652	(0.980, 59.749)	0.0523	
	Previous systemic therapy						0.3926
	With	16/180 (8.9)	2/175 (1.1)	7.778	(1.815, 33.330)	0.0057	
	Without	6/168 (3.6)	2/169 (1.2)	3.018	(0.618, 14.740)	0.1723	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.3.1.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
(Safety Analysis Set)

SOC/PT	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
SOC: Investigations - PT:Blood creatine phosphokinase increased	Age						0.1963
	< 40 years	19/228 (8.3)	10/226 (4.4)	1.883	(0.896, 3.960)	0.0951	
	>= 40 years	7/120 (5.8)	1/118 (0.8)	6.883	(0.860, 55.088)	0.0691	
	Geographic regions						0.0405
	US/PR/Canada	11/140 (7.9)	1/131 (0.8)	10.293	(1.347, 78.622)	0.0246	
	Other	15/208 (7.2)	10/213 (4.7)	1.536	(0.706, 3.341)	0.2789	
	Baseline EASI						0.2451
	< Median (26.4)	10/165 (6.1)	7/180 (3.9)	1.558	(0.607, 4.000)	0.3562	
	>= Median (26.4)	16/183 (8.7)	4/164 (2.4)	3.585	(1.223, 10.505)	0.0200	
	Baseline vIGA-AD						0.0027
	3 (Moderate)	8/174 (4.6)	9/171 (5.3)	0.874	(0.345, 2.211)	0.7754	
	4 (Severe)	18/174 (10.3)	2/173 (1.2)	8.948	(2.108, 37.981)	0.0030	
	Sex						0.9835
	Female	8/165 (4.8)	3/150 (2.0)	2.424	(0.655, 8.970)	0.1847	
	Male	18/183 (9.8)	8/194 (4.1)	2.385	(1.063, 5.351)	0.0350	
	BMI						0.0120
	< 25 kg/m2	9/161 (5.6)	10/169 (5.9)	0.945	(0.394, 2.265)	0.8986	
	>= 25 - < 30 kg/m2	11/ 93 (11.8)	0/110 (0.0)	27.160	(1.622, 454.771)	0.0217	
	>= 30 kg/m2	6/ 93 (6.5)	1/ 65 (1.5)	4.194	(0.517, 34.012)	0.1795	
	Race						0.3090
	White	14/235 (6.0)	5/244 (2.0)	2.907	(1.064, 7.945)	0.0375	
	Asian	6/ 77 (7.8)	3/ 78 (3.8)	2.026	(0.525, 7.812)	0.3052	
	Other	6/ 36 (16.7)	3/ 22 (13.6)	1.222	(0.340, 4.398)	0.7587	
	Baseline hsCRP						0.5002
	< Median (1.745)	17/161 (10.6)	9/185 (4.9)	2.170	(0.995, 4.734)	0.0515	
	>= Median(1.745)	9/187 (4.8)	2/159 (1.3)	3.826	(0.839, 17.451)	0.0831	
	Previous systemic therapy						0.7586
	With	13/180 (7.2)	6/175 (3.4)	2.106	(0.819, 5.418)	0.1222	
	Without	13/168 (7.7)	5/169 (3.0)	2.615	(0.954, 7.174)	0.0618	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.3.1.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
(Safety Analysis Set)

SOC/PT	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders	Age						0.5942
	< 40 years	85/228 (37.3)	58/226 (25.7)	1.453	(1.100, 1.919)	0.0086	
	>= 40 years	36/120 (30.0)	21/118 (17.8)	1.686	(1.049, 2.709)	0.0310	
	Geographic regions						0.2742
	US/PR/Canada	36/140 (25.7)	27/131 (20.6)	1.248	(0.805, 1.934)	0.3227	
	Other	85/208 (40.9)	52/213 (24.4)	1.674	(1.256, 2.231)	0.0004	
	Baseline EASI						0.5087
	< Median (26.4)	46/165 (27.9)	37/180 (20.6)	1.356	(0.930, 1.979)	0.1139	
	>= Median (26.4)	75/183 (41.0)	42/164 (25.6)	1.600	(1.170, 2.190)	0.0033	
	Baseline vIGA-AD						0.6433
	3 (Moderate)	49/174 (28.2)	34/171 (19.9)	1.416	(0.965, 2.078)	0.0750	
	4 (Severe)	72/174 (41.4)	45/173 (26.0)	1.591	(1.170, 2.163)	0.0031	
	Sex						0.3262
	Female	54/165 (32.7)	37/150 (24.7)	1.327	(0.930, 1.892)	0.1186	
	Male	67/183 (36.6)	42/194 (21.6)	1.691	(1.217, 2.349)	0.0017	
	BMI						0.6421
	< 25 kg/m2	66/161 (41.0)	43/169 (25.4)	1.611	(1.173, 2.214)	0.0033	
	>= 25 - < 30 kg/m2	26/ 93 (28.0)	21/110 (19.1)	1.464	(0.884, 2.425)	0.1383	
	>= 30 kg/m2	29/ 93 (31.2)	15/ 65 (23.1)	1.351	(0.790, 2.311)	0.2717	
	Race						0.3833
	White	73/235 (31.1)	54/244 (22.1)	1.404	(1.037, 1.900)	0.0282	
	Asian	38/ 77 (49.4)	17/ 78 (21.8)	2.264	(1.405, 3.650)	0.0008	
	Other	10/ 36 (27.8)	8/ 22 (36.4)	0.764	(0.356, 1.639)	0.4893	
	Baseline hsCRP						0.5654
	< Median (1.745)	51/161 (31.7)	42/185 (22.7)	1.395	(0.984, 1.979)	0.0618	
	>= Median(1.745)	70/187 (37.4)	37/159 (23.3)	1.609	(1.148, 2.255)	0.0058	
	Previous systemic therapy						0.8366
	With	76/180 (42.2)	48/175 (27.4)	1.539	(1.146, 2.068)	0.0042	
	Without	45/168 (26.8)	31/169 (18.3)	1.460	(0.974, 2.188)	0.0666	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.3.1.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
(Safety Analysis Set)

SOC/PT	Subgroup Level	Upadacitinib(N=348) n/N[s](%)	Dupilumab(N=344) n/N[s](%)	Unstratified Analysis Relative Risk	(95% CI)	p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders - PT:Acne	Age						0.2008
	< 40 years	48/228 (21.1)	10/226 (4.4)	4.758	(2.469, 9.169)	<.0001	
	>= 40 years	16/120 (13.3)	1/118 (0.8)	15.733	(2.120, 116.749)	0.0070	
	Geographic regions						0.1520
	US/PR/Canada	22/140 (15.7)	6/131 (4.6)	3.431	(1.436, 8.195)	0.0055	
	Other	42/208 (20.2)	5/213 (2.3)	8.602	(3.472, 21.313)	<.0001	
	Baseline EASI						0.4998
	< Median (26.4)	25/165 (15.2)	6/180 (3.3)	4.545	(1.913, 10.802)	0.0006	
	>= Median (26.4)	39/183 (21.3)	5/164 (3.0)	6.990	(2.823, 17.311)	<.0001	
	Baseline vIGA-AD						0.3770
	3 (Moderate)	32/174 (18.4)	7/171 (4.1)	4.493	(2.039, 9.900)	0.0002	
	4 (Severe)	32/174 (18.4)	4/173 (2.3)	7.954	(2.874, 22.012)	<.0001	
	Sex						0.1612
	Female	29/165 (17.6)	7/150 (4.7)	3.766	(1.700, 8.342)	0.0011	
	Male	35/183 (19.1)	4/194 (2.1)	9.276	(3.363, 25.584)	<.0001	
	BMI						0.7530
	< 25 kg/m2	32/161 (19.9)	7/169 (4.1)	4.799	(2.180, 10.561)	<.0001	
	>= 25 - < 30 kg/m2	16/ 93 (17.2)	0/110 (0.0)	38.968	(2.370, 640.846)	0.0104	
	>= 30 kg/m2	16/ 93 (17.2)	4/ 65 (6.2)	2.796	(0.979, 7.980)	0.0547	
	Race						0.1543
	White	32/235 (13.6)	5/244 (2.0)	6.645	(2.634, 16.764)	<.0001	
	Asian	28/ 77 (36.4)	4/ 78 (5.1)	7.091	(2.611, 19.260)	0.0001	
	Other	4/ 36 (11.1)	2/ 22 (9.1)	1.222	(0.244, 6.129)	0.8073	
	Baseline hsCRP						0.2733
	< Median (1.745)	31/161 (19.3)	8/185 (4.3)	4.453	(2.108, 9.407)	<.0001	
	>= Median(1.745)	33/187 (17.6)	3/159 (1.9)	9.353	(2.924, 29.920)	0.0002	
	Previous systemic therapy						0.2283
	With	36/180 (20.0)	4/175 (2.3)	8.750	(3.181, 24.068)	<.0001	
	Without	28/168 (16.7)	7/169 (4.1)	4.024	(1.808, 8.957)	0.0006	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.3.2
Frequent Serious Adverse Events by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

!!! There are no Observations for this Report !!!

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.2.1
Frequent Serious Adverse Events by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
(Safety Analysis Set)

!!! There are no Observations for this Report !!!

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

Table 3.3.3
Frequent Adverse Events of CTCAE Grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT		Upadacitinib (N=348)	Dupilumab (N=344)
SOC: Investigations	Number of subjects with events, n (%)	11 (3.2)	8 (2.3)
	Unstratified Analysis		
	Odds Ratio	1.371	
	95% CI	0.545, 3.451	
	p-value	0.5030	
	Relative Risk	1.359	
	95% CI	0.553, 3.338	
	p-value	0.5032	
	Risk Difference	0.008	
	95% CI	-0.016, 0.033	
	p-value	0.5009	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.

Table 3.3.3.1
Frequent Adverse Events of CTCAE Grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
(Safety Analysis Set)

!!! There are no Observations for this Report !!!

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events that begin or worsen in severity after initiation of Upadacitinib/Dupilumab through 30 days following the last dose of Upadacitinib or 84 days following the last dose of Dupilumab, regardless of any study drug interruption. MedDRA v22.0 coding dictionary applied.
N: Number of subjects, N[s]: Number of subjects in subgroup, CI: Confidence Interval, NE: Not estimable
Relative risk was constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Relative Risk was constructed using normal approximation (Wald). P-value for Relative Risk was calculated using Wald test.
p-Value for interaction from a generalized linear model with treatment, subgroup and treatment by subgroup interaction as covariates with log-link.

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Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.1
Demographic and Baseline Characteristics
(ITT_M Population)

		Upadacitinib (N=75)	Placebo (N=76)	Total (N=151)
Age (years)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	15.44 (1.93)	15.54 (1.60)	15.49 (1.77)
	Median	16.00	16.00	16.00
	Q1, Q3	14.00, 17.00	14.00, 17.00	14.00, 17.00
	Min, Max	12.00, 18.00	12.00, 18.00	12.00, 18.00
Sex - n (%)	Female	40 (53.3)	43 (56.6)	83 (55.0)
	Male	35 (46.7)	33 (43.4)	68 (45.0)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Race - n (%)	White	53 (70.7)	55 (72.4)	108 (71.5)
	Black	7 (9.3)	6 (7.9)	13 (8.6)
	Asian	9 (12.0)	11 (14.5)	20 (13.2)
	Other	6 (8.0)	4 (5.3)	10 (6.6)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Geographic Region - n (%)	US/PR/Canada	32 (42.7)	33 (43.4)	65 (43.0)
	Other	43 (57.3)	43 (56.6)	86 (57.0)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Weight (kg)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	61.18 (13.38)	64.85 (16.10)	63.02 (14.88)
	Median	57.20	61.05	60.00
	Q1, Q3	53.90, 70.00	54.00, 73.95	54.00, 71.60
	Min, Max	40.00, 110.40	40.30, 106.10	40.00, 110.40
Weight (kg) (Median M16-045: 71 , M18-891: 72.94) - n (%)	< Median	60 (80.0)	54 (71.1)	114 (75.5)
	>= Median	15 (20.0)	22 (28.9)	37 (24.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Body Mass Index (kg/m^2)	n (missing)	74 (1)	75 (1)	149 (2)
	Mean (SD)	22.62 (4.52)	23.81 (5.09)	23.22 (4.84)
	Median	21.45	22.50	21.90
	Q1, Q3	19.50, 24.40	19.70, 27.00	19.70, 25.50
	Min, Max	16.20, 36.10	16.60, 38.20	16.20, 38.20
Body Mass Index (kg/m^2) - n (%)	< 25	58 (78.4)	50 (66.7)	108 (72.5)
	25 - < 30	8 (10.8)	12 (16.0)	20 (13.4)
	>= 30	8 (10.8)	13 (17.3)	21 (14.1)
	Missing	1 (1.4)	1 (1.3)	2 (1.3)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.1
Demographic and Baseline Characteristics
(ITT_M Population)

		Upadacitinib (N=75)	Placebo (N=76)	Total (N=151)
Baseline EASI	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	30.26 (12.99)	31.47 (14.51)	30.87 (13.75)
	Median	26.70	27.75	27.40
	Q1, Q3	19.50, 36.70	19.70, 37.45	19.50, 36.70
	Min, Max	16.00, 66.00	16.10, 71.40	16.00, 71.40
Baseline EASI - n (%)	< Median (25.8)	36 (48.0)	33 (43.4)	69 (45.7)
	>= Median (25.8)	39 (52.0)	43 (56.6)	82 (54.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline vIGA-AD	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	3.48 (0.50)	3.49 (0.50)	3.48 (0.50)
	Median	3.00	3.00	3.00
	Q1, Q3	3.00, 4.00	3.00, 4.00	3.00, 4.00
	Min, Max	3.00, 4.00	3.00, 4.00	3.00, 4.00
Baseline vIGA-AD - n (%)	3 (Moderate)	39 (52.0)	39 (51.3)	78 (51.7)
	4 (Severe)	36 (48.0)	37 (48.7)	73 (48.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline hsCRP	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	2.06 (4.90)	1.88 (3.34)	1.97 (4.18)
	Median	0.69	0.69	0.69
	Q1, Q3	0.20, 1.72	0.27, 1.67	0.21, 1.72
	Min, Max	0.20, 31.60	0.20, 23.40	0.20, 31.60
Baseline hsCRP (Median M16-045: 1.4 , M18-891: 1.645) - n (%)	< Median	55 (73.3)	56 (73.7)	111 (73.5)
	>= Median	20 (26.7)	20 (26.3)	40 (26.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Topical Therapy - n (%)	With	74 (98.7)	76 (100.0)	150 (99.3)
	Without	1 (1.3)	0 (0.0)	1 (0.7)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Systemic Therapy - n (%)	With	24 (32.0)	34 (44.7)	58 (38.4)
	Without	51 (68.0)	42 (55.3)	93 (61.6)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Phototherapy - n (%)	With	12 (16.0)	15 (19.7)	27 (17.9)
	Without	63 (84.0)	61 (80.3)	124 (82.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline BSA	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	48.15 (23.05)	50.79 (22.85)	49.48 (22.91)
	Median	46.00	45.00	45.00
	Q1, Q3	28.00, 70.00	33.50, 64.50	30.50, 68.50
	Min, Max	11.00, 98.00	14.00, 98.00	11.00, 98.00

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.1
Demographic and Baseline Characteristics
(ITT_M Population)

		Upadacitinib (N=75)	Placebo (N=76)	Total (N=151)
Worst Pruritus NRS (Weekly Average)	n (missing)	74 (1)	76 (0)	150 (1)
	Mean (SD)	7.03 (1.90)	7.23 (1.74)	7.13 (1.82)
	Median	7.31	7.07	7.15
	Q1, Q3	6.00, 8.50	5.71, 8.77	5.71, 8.57
	Min, Max	1.86, 10.00	3.40, 10.00	1.86, 10.00
Baseline PGIS	n (missing)	74 (1)	75 (1)	149 (2)
	Mean (SD)	4.28 (1.13)	3.89 (1.34)	4.09 (1.25)
	Median	4.00	4.00	4.00
	Q1, Q3	4.00, 5.00	3.00, 5.00	3.00, 5.00
	Min, Max	1.00, 6.00	0.00, 6.00	0.00, 6.00
Disease duration since diagnosis (years)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	11.95 (4.47)	12.76 (4.42)	12.36 (4.45)
	Median	12.71	14.08	13.48
	Q1, Q3	8.18, 15.59	11.56, 15.87	10.47, 15.82
	Min, Max	0.61, 18.34	1.10, 17.87	0.61, 18.34
Any Allergic Comorbidity - n (%)	With	54 (72.0)	53 (69.7)	107 (70.9)
	Without	21 (28.0)	23 (30.3)	44 (29.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Food Allergy - n (%)	With	28 (37.3)	35 (46.1)	63 (41.7)
	Without	47 (62.7)	41 (53.9)	88 (58.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Asthma - n (%)	With	29 (38.7)	30 (39.5)	59 (39.1)
	Without	46 (61.3)	46 (60.5)	92 (60.9)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Allergic Rhinitis - n (%)	With	37 (49.3)	41 (53.9)	78 (51.7)
	Without	38 (50.7)	35 (46.1)	73 (48.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Eosinophilic Esophagitis - n (%)	With	0 (0.0)	1 (1.3)	1 (0.7)
	Without	75 (100.0)	75 (98.7)	150 (99.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Nasal Polyps - n (%)	With	0 (0.0)	1 (1.3)	1 (0.7)
	Without	75 (100.0)	75 (98.7)	150 (99.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.2
Subject Disposition
(ITT_M Population)

Status	Upadacitinib(N=75) n (%)	Placebo(N=76) n (%)	Total(N=151) n (%)
Received study drug in DB period	75 (100.0)	76 (100.0)	151 (100.0)
Received first rescue medication in DB period	7 (9.3)	38 (50.0)	45 (29.8)
Received first topical rescue medication in DB period	7 (9.3)	36 (47.4)	43 (28.5)
Plain topical corticosteroid in DB period	7 (9.3)	34 (44.7)	41 (27.2)
High potency topical corticosteroid in DB period	4 (5.3)	17 (22.4)	21 (13.9)
Medium potency topical corticosteroid in DB period	2 (2.7)	21 (27.6)	23 (15.2)
Low potency topical corticosteroid in DB period	3 (4.0)	11 (14.5)	14 (9.3)
Topical calcineurin inhibitor in DB period	0 (0.0)	6 (7.9)	6 (4.0)
Other topical therapy in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Received first systemic rescue medication in DB period	1 (1.3)	12 (15.8)	13 (8.6)
Biologic systemic therapy in DB period	0 (0.0)	1 (1.3)	1 (0.7)
Non-biologic immunomodulating systemic therapy in DB period	1 (1.3)	12 (15.8)	13 (8.6)
Other systemic therapy in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Received first rescue phototherapy in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Completed DB period	73 (97.3)	68 (89.5)	141 (93.4)
Ongoing DB Period	0 (0.0)	1 (1.3)	1 (0.7)
Discontinued study in DB period	2 (2.7)	7 (9.2)	9 (6.0)
Primary reason			
Adverse event	2 (2.7)	1 (1.3)	3 (2.0)
Withdrawal of consent	0 (0.0)	2 (2.6)	2 (1.3)
Lost to follow-up	0 (0.0)	1 (1.3)	1 (0.7)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	3 (3.9)	3 (2.0)
Completed DB period on study drug	73 (97.3)	68 (89.5)	141 (93.4)
Ongoing DB Period on study drug	0 (0.0)	1 (1.3)	1 (0.7)
Discontinued study drug in DB period	2 (2.7)	7 (9.2)	9 (6.0)
Primary reason			
Adverse event	1 (1.3)	1 (1.3)	2 (1.3)
Withdrawal of consent	0 (0.0)	2 (2.6)	2 (1.3)
Lost to follow-up	0 (0.0)	1 (1.3)	1 (0.7)
Lack of efficacy	1 (1.3)	3 (3.9)	4 (2.6)
EASI score - worsening of 25%	0 (0.0)	0 (0.0)	0 (0.0)
Systemic rescue	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing status, DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, COVID: Corona Virus Disease
One patient may receive more than one rescue therapy (topical, systemic, phototherapy).
If a patient receives systemic rescue therapy the primary reason for discontinuation of study drug does not necessarily have to be systemic rescue.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.2
Subject Disposition
(ITT_M Population)

Status	Upadacitinib(N=75) n (%)	Placebo(N=76) n (%)	Total(N=151) n (%)
Entered BE period	73 (97.3)	68 (89.5)	141 (93.4)
Received study drug in BE period	73 (97.3)	68 (89.5)	141 (93.4)
Received first rescue medication in BE period	2 (2.7)	1 (1.3)	3 (2.0)
Received first topical rescue medication in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Plain topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
High potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Medium potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Low potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Topical calcineurin inhibitor in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Other topical therapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Received first systemic rescue medication in BE period	2 (2.7)	1 (1.3)	3 (2.0)
Biologic systemic therapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Non-biologic immunomodulating systemic therapy in BE period	2 (2.7)	1 (1.3)	3 (2.0)
Other systemic therapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Received first rescue phototherapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Ongoing BE Period	67 (89.3)	66 (86.8)	133 (88.1)
Discontinued Study in BE period	6 (8.0)	2 (2.6)	8 (5.3)
Primary reason			
Adverse event	1 (1.3)	1 (1.3)	2 (1.3)
Withdrawal of consent	4 (5.3)	0 (0.0)	4 (2.6)
Lost to follow-up	1 (1.3)	1 (1.3)	2 (1.3)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Ongoing study drug in BE period	67 (89.3)	66 (86.8)	133 (88.1)
Discontinued study drug in BE Period	6 (8.0)	2 (2.6)	8 (5.3)
Primary reason			
Adverse event	1 (1.3)	1 (1.3)	2 (1.3)
Withdrawal of consent	2 (2.7)	0 (0.0)	2 (1.3)
Lost to follow-up	1 (1.3)	1 (1.3)	2 (1.3)
Lack of efficacy	2 (2.7)	0 (0.0)	2 (1.3)
EASI score - worsening of 25%	0 (0.0)	0 (0.0)	0 (0.0)
Systemic rescue	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing status, DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, COVID: Corona Virus Disease
One patient may receive more than one rescue therapy (topical, systemic, phototherapy).
If a patient receives systemic rescue therapy the primary reason for discontinuation of study drug does not necessarily have to be systemic rescue.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.3
Duration of Study and Treatment and Endpoint Observation time at Week 16
(ITT_M Population)

		Upadacitinib (N=75)	Placebo (N=76)	Total (N=151)
Study duration in DB period (Week 0 - 16) (Weeks)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	16.07 (0.54)	15.26 (3.12)	15.66 (2.28)
	Median	16.00	16.00	16.00
	Q1, Q3	16.00, 16.14	15.86, 16.14	15.86, 16.14
	Min, Max	14.43, 18.71	2.29, 19.14	2.29, 19.14
Treatment duration in DB period (Week 0 - 16) (Weeks)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	15.89 (1.18)	14.85 (3.98)	15.37 (2.98)
	Median	16.00	16.00	16.00
	Q1, Q3	15.86, 16.14	15.79, 16.14	15.86, 16.14
	Min, Max	8.86, 18.71	0.43, 17.43	0.43, 18.71
Observation time for safety at Week 16 (Weeks)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	16.20 (0.63)	15.39 (2.84)	15.79 (2.10)
	Median	16.14	16.14	16.14
	Q1, Q3	16.14, 16.29	15.93, 16.29	16.00, 16.29
	Min, Max	13.14, 18.86	4.71, 19.29	4.71, 19.29
Body Surface Area (BSA): Observation time at Week 16 (Weeks)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	16.07 (1.17)	13.48 (5.29)	14.77 (4.05)
	Median	16.14	16.14	16.14
	Q1, Q3	16.14, 16.29	15.71, 16.14	16.00, 16.29
	Min, Max	8.14, 18.86	1.14, 17.29	1.14, 18.86
Eczema Area and Severity Index (EASI): Observation time at Week 16 (Weeks)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	16.07 (1.17)	13.48 (5.29)	14.77 (4.05)
	Median	16.14	16.14	16.14
	Q1, Q3	16.14, 16.29	15.71, 16.14	16.00, 16.29
	Min, Max	8.14, 18.86	1.14, 17.29	1.14, 18.86
Patient Global Impression of Severity (PGIS): Observation time at Week 16 (Weeks)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	16.02 (1.56)	13.57 (5.33)	14.79 (4.12)
	Median	16.14	16.14	16.14
	Q1, Q3	16.14, 16.29	15.79, 16.14	16.00, 16.29
	Min, Max	4.14, 18.86	1.14, 19.29	1.14, 19.29
Worst Pruritus NRS: Observation time at Week 16 (Weeks)	n (missing)	75 (0)	76 (0)	151 (0)
	Mean (SD)	15.38 (2.41)	13.51 (5.06)	14.44 (4.06)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.14	14.71, 16.14	15.86, 16.14
	Min, Max	0.14, 16.29	0.14, 17.71	0.14, 17.71

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, NRS: Numeric Rating Scale
Study duration is calculated as (date of first dose of study drug - minimum(date of first dose of study drug in BE period, date of end of study) + 1) divided by 7
Treatment duration is calculated as (date of first dose of study drug - date of last dose of study drug in DB period + 1) divided by 7
Observation time for Safety is calculated as (date of first dose of study drug - minimum(date of first dose of study drug in BE period, date of last dose of study drug in DB period + 30) + 1) divided by 7
Observation time for endpoints is calculated as (date of first dose of study drug - date of last non-missing evaluation in DB period + 1) divided by 7. Evaluations after start of systemic rescue or phototherapy are excluded.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.4
Overview Completion Rates
(ITT_M Population)

Endpoint	Visit	Upadacitinib(N=75) n (%)	Placebo(N=76) n (%)
Worst Pruritus Numeric Rating Scale	Baseline	74 (98.7)	76 (100.0)
	Week 1	74 (98.7)	76 (100.0)
	Week 2	73 (97.3)	75 (98.7)
	Week 3	73 (97.3)	72 (94.7)
	Week 4	72 (96.0)	70 (92.1)
	Week 5	72 (96.0)	68 (89.5)
	Week 6	73 (97.3)	69 (90.8)
	Week 7	74 (98.7)	68 (89.5)
	Week 8	73 (97.3)	67 (88.2)
	Week 9	72 (96.0)	67 (88.2)
	Week 10	69 (92.0)	68 (89.5)
	Week 11	68 (90.7)	67 (88.2)
	Week 12	68 (90.7)	68 (89.5)
	Week 13	69 (92.0)	66 (86.8)
	Week 14	69 (92.0)	66 (86.8)
	Week 15	68 (90.7)	63 (82.9)
	Week 16	63 (84.0)	64 (84.2)
Patient Global Impression of Severity (PGIS)	Baseline	74 (98.7)	75 (98.7)
	Week 1	71 (94.7)	67 (88.2)
	Week 2	74 (98.7)	74 (97.4)
	Week 4	72 (96.0)	71 (93.4)
	Week 12	74 (98.7)	66 (86.8)
	Week 16	73 (97.3)	68 (89.5)

N: Number of subjects, n: Number of subjects with non missing values
All observed data will be used in the analysis.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)

Table 1.5

Overview Missings and Rescue Therapy at Week 16

(ITT_M Population)

		Upadacitinib(N=75)							Placebo(N=76)						
		missings			rescue therapy				missings			rescue therapy			
Endpoint	Visit	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)
EASI	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	3 (4.0)	3 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.6)	5 (6.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)	0 (0.0)	4 (5.3)	2 (2.6)	2 (2.6)	0 (0.0)
	Week 4	2 (2.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.6)	5 (6.6)	0 (0.0)	2 (2.6)	0 (0.0)	2 (2.6)	0 (0.0)
	Week 8	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (9.2)	7 (9.2)	0 (0.0)	28 (36.8)	20 (26.3)	8 (10.5)	0 (0.0)
	Week 12	1 (1.3)	1 (1.3)	0 (0.0)	3 (4.0)	2 (2.7)	1 (1.3)	0 (0.0)	8 (10.5)	8 (10.5)	0 (0.0)	31 (40.8)	23 (30.3)	8 (10.5)	0 (0.0)
	Week 16	2 (2.7)	2 (2.7)	0 (0.0)	5 (6.7)	5 (6.7)	0 (0.0)	0 (0.0)	9 (11.8)	7 (9.2)	2 (2.6)	33 (43.4)	25 (32.9)	8 (10.5)	0 (0.0)
Pruritus	Baseline	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	1 (1.3)	1 (1.3)	0 (0.0)
	Week 2	2 (2.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)	0 (0.0)	5 (6.6)	3 (3.9)	2 (2.6)	0 (0.0)
	Week 3	2 (2.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (5.3)	4 (5.3)	0 (0.0)	4 (5.3)	0 (0.0)	4 (5.3)	0 (0.0)
	Week 4	3 (4.0)	3 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (7.9)	6 (7.9)	0 (0.0)	3 (3.9)	0 (0.0)	3 (3.9)	0 (0.0)
	Week 5	3 (4.0)	3 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (10.5)	8 (10.5)	0 (0.0)	21 (27.6)	17 (22.4)	4 (5.3)	0 (0.0)
	Week 6	2 (2.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (9.2)	7 (9.2)	0 (0.0)	23 (30.3)	18 (23.7)	5 (6.6)	0 (0.0)
	Week 7	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (10.5)	8 (10.5)	0 (0.0)	24 (31.6)	18 (23.7)	6 (7.9)	0 (0.0)
	Week 8	2 (2.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (11.8)	9 (11.8)	0 (0.0)	26 (34.2)	18 (23.7)	8 (10.5)	0 (0.0)
	Week 9	3 (4.0)	3 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (11.8)	9 (11.8)	0 (0.0)	29 (38.2)	21 (27.6)	8 (10.5)	0 (0.0)
	Week 10	6 (8.0)	6 (8.0)	0 (0.0)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	8 (10.5)	8 (10.5)	0 (0.0)	29 (38.2)	21 (27.6)	8 (10.5)	0 (0.0)
	Week 11	7 (9.3)	7 (9.3)	0 (0.0)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	9 (11.8)	9 (11.8)	0 (0.0)	28 (36.8)	20 (26.3)	8 (10.5)	0 (0.0)
	Week 12	7 (9.3)	7 (9.3)	0 (0.0)	2 (2.7)	2 (2.7)	0 (0.0)	0 (0.0)	8 (10.5)	8 (10.5)	0 (0.0)	29 (38.2)	21 (27.6)	8 (10.5)	0 (0.0)
	Week 13	6 (8.0)	6 (8.0)	0 (0.0)	5 (6.7)	5 (6.7)	0 (0.0)	0 (0.0)	10 (13.2)	10 (13.2)	0 (0.0)	31 (40.8)	23 (30.3)	8 (10.5)	0 (0.0)
	Week 14	6 (8.0)	6 (8.0)	0 (0.0)	5 (6.7)	5 (6.7)	0 (0.0)	0 (0.0)	10 (13.2)	10 (13.2)	0 (0.0)	31 (40.8)	23 (30.3)	8 (10.5)	0 (0.0)
	Week 15	7 (9.3)	7 (9.3)	0 (0.0)	5 (6.7)	5 (6.7)	0 (0.0)	0 (0.0)	13 (17.1)	13 (17.1)	0 (0.0)	28 (36.8)	20 (26.3)	8 (10.5)	0 (0.0)
	Week 16	12 (16.0)	12 (16.0)	0 (0.0)	4 (5.3)	4 (5.3)	0 (0.0)	0 (0.0)	12 (15.8)	12 (15.8)	0 (0.0)	29 (38.2)	21 (27.6)	8 (10.5)	0 (0.0)
BSA	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	3 (4.0)	3 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.6)	5 (6.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)	0 (0.0)	4 (5.3)	2 (2.6)	2 (2.6)	0 (0.0)
	Week 4	2 (2.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (7.9)	6 (7.9)	0 (0.0)	2 (2.6)	0 (0.0)	2 (2.6)	0 (0.0)
	Week 8	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (10.5)	8 (10.5)	0 (0.0)	27 (35.5)	19 (25.0)	8 (10.5)	0 (0.0)
	Week 12	2 (2.7)	2 (2.7)	0 (0.0)	3 (4.0)	2 (2.7)	1 (1.3)	0 (0.0)	8 (10.5)	8 (10.5)	0 (0.0)	31 (40.8)	23 (30.3)	8 (10.5)	0 (0.0)
	Week 16	2 (2.7)	2 (2.7)	0 (0.0)	5 (6.7)	5 (6.7)	0 (0.0)	0 (0.0)	9 (11.8)	7 (9.2)	2 (2.6)	33 (43.4)	25 (32.9)	8 (10.5)	0 (0.0)
PGIS	Baseline	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	4 (5.3)	4 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (11.8)	9 (11.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)	0 (0.0)	4 (5.3)	2 (2.6)	2 (2.6)	0 (0.0)
	Week 4	3 (4.0)	3 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.6)	5 (6.6)	0 (0.0)	2 (2.6)	0 (0.0)	2 (2.6)	0 (0.0)
	Week 12	1 (1.3)	1 (1.3)	0 (0.0)	3 (4.0)	2 (2.7)	1 (1.3)	0 (0.0)	10 (13.2)	10 (13.2)	0 (0.0)	30 (39.5)	22 (28.9)	8 (10.5)	0 (0.0)
	Week 16	2 (2.7)	2 (2.7)	0 (0.0)	5 (6.7)	5 (6.7)	0 (0.0)	0 (0.0)	8 (10.5)	7 (9.2)	1 (1.3)	33 (43.4)	25 (32.9)	8 (10.5)	0 (0.0)

N: Number of subjects, EASI: Eczema Area and Severity Index, BSA: Body Surface Area, PGIS: Patient Global Impression of Severity
COVID summarizes the number of subjects with missing data due to COVID-19 infection or logistical restriction, No-COVID summarizes all other subjects with missing data.
topical summarizes the number of rescued subjects of the following categories: plain topical corticosteroids, high/medium/low potency topical corticosteroids, topical calcineurin inhibitor, other topical therapy
systemic summarizes the number of rescued subjects of the following categories: biologic systemic therapy, non-biologic immunomodulating systemic therapy, other systemic therapy
photo summarizes the number of rescued subjects with phototherapy.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.1.1
Descriptive Statistics for Mean Values and Change from Baseline - Eczema Area and Severity Index (EASI)
(ITT_M Population)

	Upadacitinib(N=75)					Placebo(N=76)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	75	0 (0.0)	30.26 (12.99)			76	0 (0.0)	31.47 (14.51)		
Week 1	72	3 (4.0)	19.28 (11.95)	72	-11.13 (11.78)	71	5 (6.6)	30.11 (13.79)	71	-1.75 (9.72)
Week 2	75	0 (0.0)	12.33 (10.91)	75	-17.93 (11.43)	72	4 (5.3)	28.72 (15.30)	72	-2.88 (10.27)
Week 4	73	2 (2.7)	8.03 (9.95)	73	-22.38 (11.61)	69	7 (9.2)	27.03 (17.04)	69	-4.98 (9.79)
Week 8	74	1 (1.3)	6.26 (10.19)	74	-24.18 (12.55)	61	15 (19.7)	20.20 (14.49)	61	-9.96 (11.75)
Week 12	73	2 (2.7)	7.15 (10.21)	73	-23.20 (13.42)	60	16 (21.1)	17.95 (14.48)	60	-12.37 (14.75)
Week 16	73	2 (2.7)	6.18 (8.17)	73	-24.24 (13.03)	59	17 (22.4)	17.59 (13.96)	59	-12.66 (12.51)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.1.2
Descriptive Statistics for Mean Values and Change from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT_M Population)

	Upadacitinib(N=75)				Placebo(N=76)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	n	n_miss (%) Mean (SD)	n	Mean (SD)	n	n_miss (%) Mean (SD)	n	Mean (SD)
Baseline	74	1 (1.3) 7.03 (1.90)			76	0 (0.0) 7.23 (1.74)		
Week 1	74	1 (1.3) 5.48 (1.96)	73	-1.55 (1.92)	75	1 (1.3) 6.96 (1.94)	75	-0.23 (1.08)
Week 2	73	2 (2.7) 4.36 (2.41)	72	-2.66 (2.54)	73	3 (3.9) 6.73 (2.10)	73	-0.50 (1.40)
Week 3	73	2 (2.7) 3.82 (2.65)	72	-3.29 (2.80)	68	8 (10.5) 6.54 (2.25)	68	-0.75 (1.53)
Week 4	72	3 (4.0) 3.58 (2.82)	71	-3.53 (2.99)	67	9 (11.8) 6.41 (2.12)	67	-0.87 (1.66)
Week 5	72	3 (4.0) 3.39 (2.84)	71	-3.65 (2.91)	64	12 (15.8) 5.80 (2.41)	64	-1.51 (2.22)
Week 6	73	2 (2.7) 3.39 (2.76)	72	-3.63 (2.82)	64	12 (15.8) 5.38 (2.63)	64	-1.93 (2.53)
Week 7	74	1 (1.3) 3.14 (2.64)	73	-3.86 (2.68)	62	14 (18.4) 5.38 (2.62)	62	-1.96 (2.58)
Week 8	73	2 (2.7) 3.24 (2.81)	72	-3.71 (2.79)	59	17 (22.4) 5.31 (2.63)	59	-2.03 (2.57)
Week 9	72	3 (4.0) 3.28 (2.73)	71	-3.70 (2.77)	59	17 (22.4) 5.21 (2.71)	59	-2.12 (2.58)
Week 10	69	6 (8.0) 3.14 (2.68)	68	-3.82 (2.80)	60	16 (21.1) 5.05 (2.62)	60	-2.19 (2.62)
Week 11	68	7 (9.3) 3.35 (2.67)	68	-3.60 (2.78)	59	17 (22.4) 5.12 (2.62)	59	-2.16 (2.61)
Week 12	68	7 (9.3) 3.49 (2.72)	68	-3.55 (2.78)	60	16 (21.1) 5.06 (2.50)	60	-2.21 (2.51)
Week 13	69	6 (8.0) 3.13 (2.76)	69	-3.82 (2.80)	58	18 (23.7) 5.20 (2.47)	58	-2.10 (2.41)
Week 14	69	6 (8.0) 3.23 (2.79)	69	-3.71 (2.91)	58	18 (23.7) 5.20 (2.64)	58	-2.02 (2.51)
Week 15	68	7 (9.3) 3.29 (2.77)	68	-3.61 (2.87)	55	21 (27.6) 5.06 (2.66)	55	-2.08 (2.55)
Week 16	63	12 (16.0) 3.33 (2.77)	63	-3.59 (2.95)	56	20 (26.3) 5.07 (2.66)	56	-2.16 (2.59)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.1.3
Descriptive Statistics for Mean Values and Change from Baseline - Body Surface Area (BSA)
(ITT_M Population)

	Upadacitinib(N=75)					Placebo(N=76)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	75	0 (0.0)	48.15 (23.05)			76	0 (0.0)	50.79 (22.85)		
Week 1	72	3 (4.0)	37.18 (22.94)	72	-11.47 (16.45)	71	5 (6.6)	48.53 (22.52)	71	-2.73 (11.55)
Week 2	75	0 (0.0)	26.96 (21.22)	75	-21.19 (19.51)	72	4 (5.3)	49.94 (24.13)	72	-1.01 (13.39)
Week 4	73	2 (2.7)	19.63 (20.27)	73	-28.64 (22.65)	68	8 (10.5)	48.26 (25.41)	68	-3.86 (15.79)
Week 8	74	1 (1.3)	13.75 (19.53)	74	-34.71 (23.09)	60	16 (21.1)	37.92 (24.50)	60	-11.46 (22.60)
Week 12	72	3 (4.0)	15.29 (19.33)	72	-33.69 (24.33)	60	16 (21.1)	35.88 (24.78)	60	-13.19 (23.78)
Week 16	73	2 (2.7)	14.39 (17.09)	73	-33.64 (23.36)	59	17 (22.4)	34.73 (24.50)	59	-14.65 (21.43)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.1.4
Descriptive Statistics for Mean Values and Change from Baseline - Patient Global Impression of Severity (PGIS)
(ITT_M Population)

	Upadacitinib(N=75)					Placebo(N=76)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	74	1 (1.3)	4.28 (1.13)			75	1 (1.3)	3.89 (1.34)		
Week 1	71	4 (5.3)	2.62 (1.41)	71	-1.66 (1.28)	67	9 (11.8)	3.69 (1.52)	66	-0.30 (1.41)
Week 2	74	1 (1.3)	2.19 (1.25)	74	-2.09 (1.26)	72	4 (5.3)	3.65 (1.44)	71	-0.32 (1.19)
Week 4	72	3 (4.0)	1.89 (1.37)	72	-2.38 (1.41)	69	7 (9.2)	3.51 (1.54)	68	-0.43 (1.42)
Week 12	73	2 (2.7)	1.89 (1.42)	72	-2.38 (1.61)	58	18 (23.7)	2.79 (1.52)	57	-1.16 (1.82)
Week 16	73	2 (2.7)	1.86 (1.50)	72	-2.40 (1.80)	60	16 (21.1)	2.85 (1.52)	59	-1.08 (1.67)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.2.1
Mixed Effects Model with Repeated Measure for Changes from Baseline - Eczema Area and Severity Index (EASI)
(ITT_M Population)

	Upadacitinib(N=75)			Placebo(N=76)			Difference of LSMeans (95% CI)						Interaction
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)				p-Value	Hedge`s g (95% CI)	p-Value	p-Value
Week 1			-11.08 (1.11)			-1.40 (1.11)	-9.68 (	-12.78,	-6.58)				
Week 2			-18.09 (1.13)			-2.49 (1.13)	-15.60 (	-18.76,	-12.45)				
Week 4			-22.34 (1.15)			-4.30 (1.17)	-18.04 (	-21.29,	-14.79)				
Week 8			-24.21 (1.21)			-9.44 (1.29)	-14.77 (	-18.28,	-11.27)				
Week 12			-23.19 (1.35)			-11.95 (1.45)	-11.24 (	-15.17,	-7.32)				
Week 16			-24.08 (1.19)			-12.15 (1.28)	-11.93 (	-15.38,	-8.47)				
Overall up to Week 16	75	0	-20.50 (0.96)	76	0	-6.95 (0.98)	-13.55 (	-16.25,	-10.84)	<.0001	-1.60 (-1.97, -1.23)	<.0001	0.7579

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, study, visit and interaction between treatment and visit.
p-Value for interaction from test for heterogeneity of the differences of LSMeans in the studies using Cochrane`s Q statistic.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.2.2
Mixed Effects Model with Repeated Measure for Changes from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT_M Population)

	Upadacitinib(N=75)			Placebo(N=76)			Difference of						Interaction
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)	LSMeans (95% CI)			p-Value	Hedge`s g (95% CI)	p-Value	p-Value
Week 1			-1.55 (0.17)			-0.19 (0.17)	-1.36 (	-1.83,	-0.89)				
Week 2			-2.68 (0.23)			-0.47 (0.22)	-2.22 (	-2.84,	-1.59)				
Week 3			-3.28 (0.25)			-0.60 (0.25)	-2.68 (	-3.38,	-1.98)				
Week 4			-3.53 (0.27)			-0.68 (0.27)	-2.84 (	-3.59,	-2.10)				
Week 5			-3.66 (0.28)			-1.26 (0.29)	-2.40 (	-3.20,	-1.60)				
Week 6			-3.64 (0.30)			-1.67 (0.30)	-1.98 (	-2.81,	-1.14)				
Week 7			-3.87 (0.29)			-1.67 (0.30)	-2.20 (	-3.01,	-1.38)				
Week 8			-3.77 (0.31)			-1.79 (0.32)	-1.99 (	-2.86,	-1.12)				
Week 9			-3.66 (0.30)			-1.85 (0.31)	-1.81 (	-2.66,	-0.96)				
Week 10			-3.75 (0.30)			-2.01 (0.31)	-1.74 (	-2.58,	-0.90)				
Week 11			-3.60 (0.30)			-1.93 (0.31)	-1.67 (	-2.51,	-0.82)				
Week 12			-3.59 (0.29)			-2.04 (0.30)	-1.55 (	-2.37,	-0.72)				
Week 13			-3.87 (0.29)			-1.97 (0.30)	-1.89 (	-2.73,	-1.06)				
Week 14			-3.78 (0.30)			-1.88 (0.31)	-1.90 (	-2.76,	-1.05)				
Week 15			-3.75 (0.30)			-1.91 (0.32)	-1.84 (	-2.70,	-0.97)				
Week 16			-3.67 (0.31)			-1.94 (0.32)	-1.73 (	-2.61,	-0.86)				
Overall up to Week 16	73	2	-3.48 (0.25)	75	1	-1.49 (0.25)	-1.99 (	-2.68,	-1.29)	<.0001	-0.92 (-1.26, -0.58)	<.0001	0.9323

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, study, visit and interaction between treatment and visit.
p-Value for interaction from test for heterogeneity of the differences of LSMeans in the studies using Cochrane`s Q statistic.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.2.3
Mixed Effects Model with Repeated Measure for Changes from Baseline - Body Surface Area (BSA)
(ITT_M Population)

	Upadacitinib(N=75)			Placebo(N=76)			Difference of LSMeans (95% CI)						Interaction
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)				p-Value	Hedge`s g (95% CI)	p-Value	p-Value
Week 1			-11.34 (1.59)			-2.22 (1.59)	-9.12 (	-13.56,	-4.68)				
Week 2			-21.41 (1.81)			-0.57 (1.82)	-20.83 (	-25.90,	-15.77)				
Week 4			-28.64 (2.06)			-2.86 (2.10)	-25.78 (	-31.59,	-19.98)				
Week 8			-34.63 (2.33)			-9.96 (2.48)	-24.67 (	-31.40,	-17.93)				
Week 12			-33.16 (2.44)			-12.76 (2.62)	-20.41 (	-27.49,	-13.33)				
Week 16			-33.39 (2.25)			-13.45 (2.44)	-19.94 (	-26.50,	-13.38)				
Overall up to Week 16	75	0	-27.10 (1.65)	76	0	-6.97 (1.71)	-20.12 (	-24.82,	-15.43)	<.0001	-1.37 (-1.73, -1.02)	<.0001	0.9271

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, study, visit and interaction between treatment and visit.
p-Value for interaction from test for heterogeneity of the differences of LSMeans in the studies using Cochrane`s Q statistic.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.2.4
Mixed Effects Model with Repeated Measure for Changes from Baseline - Patient Global Impression of Severity (PGIS)
(ITT_M Population)

	Upadacitinib(N=75)			Placebo(N=76)			Difference of LSMeans (95% CI)						Interaction
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)				p-Value	Hedge`s g (95% CI)	p-Value	p-Value
Week 1			-1.60 (0.15)			-0.40 (0.15)	-1.20 (	-1.63,	-0.78)				
Week 2			-2.02 (0.13)			-0.39 (0.14)	-1.62 (	-2.00,	-1.24)				
Week 4			-2.29 (0.15)			-0.49 (0.16)	-1.80 (	-2.24,	-1.37)				
Week 12			-2.31 (0.18)			-1.18 (0.19)	-1.13 (	-1.64,	-0.61)				
Week 16			-2.34 (0.18)			-1.15 (0.20)	-1.19 (	-1.72,	-0.67)				
Overall up to Week 16	74	1	-2.11 (0.12)	75	1	-0.72 (0.12)	-1.39 (	-1.73,	-1.05)	<.0001	-1.32 (-1.67, -0.96)	<.0001	0.4220

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, study, visit and interaction between treatment and visit.
p-Value for interaction from test for heterogeneity of the differences of LSMeans in the studies using Cochrane`s Q statistic.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.1
Eczema Area and Severity Index (EASI) 75 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	5 (6.7)	2 (2.6)
	Number of imputations (NRI), n (%)	3 (4.0)	5 (6.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	26 (34.7)	2 (2.6)
	Number of imputations (NRI), n (%)	0 (0.0)	4 (5.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	48 (64.0)	5 (6.6)
	Number of imputations (NRI), n (%)	2 (2.7)	7 (9.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	57 (76.0)	8 (10.5)
	Number of imputations (NRI), n (%)	1 (1.3)	15 (19.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	53 (70.7)	11 (14.5)
	Number of imputations (NRI), n (%)	2 (2.7)	16 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	54 (72.0)	11 (14.9)
	Number of imputations (NRI), n (%)	2 (2.7)	15 (19.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	2 (2.6)
	Adjusted Analysis		
	Odds Ratio	15.227	
	95% CI	6.661, 34.809	
	p-value	<.0001	
	Relative Risk	4.893	
	95% CI	2.794, 8.569	
	p-value	<.0001	
	Risk Difference	0.573	
	95% CI	0.443, 0.702	
	p-value	<.0001	
	Interaction p-value	0.0517	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.2
Eczema Area and Severity Index (EASI) 90 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	1 (1.3)	0 (0.0)
	Number of imputations (NRI), n (%)	3 (4.0)	5 (6.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	9 (12.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	4 (5.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	23 (30.7)	1 (1.3)
	Number of imputations (NRI), n (%)	2 (2.7)	7 (9.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	36 (48.0)	2 (2.6)
	Number of imputations (NRI), n (%)	1 (1.3)	15 (19.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	30 (40.0)	2 (2.6)
	Number of imputations (NRI), n (%)	2 (2.7)	16 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	34 (45.3)	2 (2.8)
	Number of imputations (NRI), n (%)	2 (2.7)	15 (19.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	2 (2.6)
	Adjusted Analysis		
	Odds Ratio	29.629	
	95% CI	6.758, 129.900	
	p-value	<.0001	
	Relative Risk	16.546	
	95% CI	4.125, 66.362	
	p-value	<.0001	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.9120	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.3
Eczema Area and Severity Index (EASI) 100 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	3 (4.0)	5 (6.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	4 (5.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (2.7)	7 (9.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	7 (9.3)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (1.3)	15 (19.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	14 (18.7)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (2.7)	16 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	8 (10.7)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (2.7)	15 (19.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	2 (2.6)
	Adjusted Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	8 (10.7)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (1.3)	1 (1.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	23 (30.7)	1 (1.3)
	Number of imputations (NRI), n (%)	2 (2.7)	3 (3.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 3	Number of subjects with Response, n (%)	29 (38.7)	3 (3.9)
	Number of imputations (NRI), n (%)	2 (2.7)	8 (10.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	29 (38.7)	2 (2.6)
	Number of imputations (NRI), n (%)	3 (4.0)	9 (11.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 5	Number of subjects with Response, n (%)	33 (44.0)	8 (10.5)
	Number of imputations (NRI), n (%)	3 (4.0)	12 (15.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 6	Number of subjects with Response, n (%)	32 (42.7)	11 (14.5)
	Number of imputations (NRI), n (%)	2 (2.7)	12 (15.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 7	Number of subjects with Response, n (%)	38 (50.7)	12 (15.8)
	Number of imputations (NRI), n (%)	1 (1.3)	14 (18.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	35 (46.7)	14 (18.4)
	Number of imputations (NRI), n (%)	2 (2.7)	17 (22.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 9	Number of subjects with Response, n (%)	33 (44.0)	12 (15.8)
	Number of imputations (NRI), n (%)	3 (4.0)	17 (22.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 10	Number of subjects with Response, n (%)	32 (42.7)	14 (18.4)
	Number of imputations (NRI), n (%)	6 (8.0)	16 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 11	Number of subjects with Response, n (%)	28 (37.3)	13 (17.1)
	Number of imputations (NRI), n (%)	7 (9.3)	17 (22.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	28 (37.3)	13 (17.1)
	Number of imputations (NRI), n (%)	7 (9.3)	16 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 13	Number of subjects with Response, n (%)	31 (41.3)	10 (13.2)
	Number of imputations (NRI), n (%)	6 (8.0)	18 (23.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 14	Number of subjects with Response, n (%)	29 (38.7)	11 (14.5)
	Number of imputations (NRI), n (%)	6 (8.0)	18 (23.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 15	Number of subjects with Response, n (%)	31 (41.3)	11 (14.5)
	Number of imputations (NRI), n (%)	7 (9.3)	21 (27.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	29 (38.7)	12 (15.8)
	Number of imputations (NRI), n (%)	12 (16.0)	20 (26.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	3.453	
	95% CI	1.566, 7.617	
	p-value	0.0021	
	Relative Risk	2.342	
	95% CI	1.304, 4.204	
	p-value	0.0044	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.3543	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (1.3)	1 (1.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (2.7)	3 (3.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 3	Number of subjects with Response, n (%)	2 (2.7)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (2.7)	8 (10.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	8 (10.7)	0 (0.0)
	Number of imputations (NRI), n (%)	3 (4.0)	9 (11.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 5	Number of subjects with Response, n (%)	9 (12.0)	0 (0.0)
	Number of imputations (NRI), n (%)	3 (4.0)	12 (15.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 6	Number of subjects with Response, n (%)	9 (12.0)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (2.7)	12 (15.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 7	Number of subjects with Response, n (%)	11 (14.7)	2 (2.6)
	Number of imputations (NRI), n (%)	1 (1.3)	14 (18.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	13 (17.3)	1 (1.3)
	Number of imputations (NRI), n (%)	2 (2.7)	17 (22.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 9	Number of subjects with Response, n (%)	15 (20.0)	2 (2.6)
	Number of imputations (NRI), n (%)	3 (4.0)	17 (22.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 10	Number of subjects with Response, n (%)	10 (13.3)	3 (3.9)
	Number of imputations (NRI), n (%)	6 (8.0)	16 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 11	Number of subjects with Response, n (%)	8 (10.7)	3 (3.9)
	Number of imputations (NRI), n (%)	7 (9.3)	17 (22.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	11 (14.7)	3 (3.9)
	Number of imputations (NRI), n (%)	7 (9.3)	16 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 13	Number of subjects with Response, n (%)	11 (14.7)	2 (2.6)
	Number of imputations (NRI), n (%)	6 (8.0)	18 (23.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 14	Number of subjects with Response, n (%)	12 (16.0)	1 (1.3)
	Number of imputations (NRI), n (%)	6 (8.0)	18 (23.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 15	Number of subjects with Response, n (%)	15 (20.0)	2 (2.6)
	Number of imputations (NRI), n (%)	7 (9.3)	21 (27.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	11 (14.7)	2 (2.6)
	Number of imputations (NRI), n (%)	12 (16.0)	20 (26.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	6.459	
	95% CI	1.374, 30.374	
	p-value	0.0182	
	Relative Risk	5.617	
	95% CI	1.290, 24.454	
	p-value	0.0215	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.0757	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.6
Body Surface Area (BSA) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	3 (4.0)	5 (6.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	4 (5.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (2.7)	8 (10.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	7 (9.3)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (1.3)	16 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	14 (18.7)	0 (0.0)
	Number of imputations (NRI), n (%)	3 (4.0)	16 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	8 (10.7)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (2.7)	15 (19.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	2 (2.6)
	Adjusted Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.7
Patient Global Impression of Severity (PGIS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	3 (4.0)	1 (1.3)
	Number of imputations (NRI), n (%)	4 (5.3)	9 (11.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	4 (5.3)	1 (1.3)
	Number of imputations (NRI), n (%)	1 (1.3)	4 (5.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	11 (14.7)	0 (0.0)
	Number of imputations (NRI), n (%)	3 (4.0)	7 (9.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	14 (18.7)	3 (3.9)
	Number of imputations (NRI), n (%)	2 (2.7)	18 (23.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	13 (17.3)	5 (5.9)
	Number of imputations (NRI), n (%)	2 (2.7)	15 (19.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	1 (1.3)
	Adjusted Analysis		
	Odds Ratio	3.402	
	95% CI	1.067, 10.849	
	p-value	0.0385	
	Relative Risk	2.961	
	95% CI	1.034, 8.480	
	p-value	0.0432	
	Risk Difference	0.123	
	95% CI	0.018, 0.228	
	p-value	0.0214	
	Interaction p-value	0.5078	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.1
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 75 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	5 (6.9)	2 (2.6)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	3 (4.0)	5 (6.6)
Week 2	Number of subjects with Response, n (%)	26 (34.7)	2 (2.6)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	0 (0.0)	2 (2.6)
Week 4	Number of subjects with Response, n (%)	48 (63.8)	5 (6.8)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	2 (2.7)	5 (6.6)
Week 8	Number of subjects with Response, n (%)	57 (76.3)	9 (11.4)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	1 (1.3)	7 (9.2)
Week 12	Number of subjects with Response, n (%)	53 (71.2)	12 (15.2)
	Number of imputations (NRI), n (%)	1 (1.3)	8 (10.5)
	Number of imputations (MI), n (%)	1 (1.3)	8 (10.5)
Week 16	Number of subjects with Response, n (%)	54 (72.3)	12 (16.0)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	2 (2.7)	9 (11.8)
	Adjusted Analysis		
	Odds Ratio	14.220	
	95% CI	6.251, 32.351	
	p-value	<.0001	
	Relative Risk	4.576	
	95% CI	2.646, 7.914	
	p-value	<.0001	
	Risk Difference	0.564	
	95% CI	0.432, 0.696	
	p-value	<.0001	
	Interaction p-value	0.0861	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.2
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 90 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	1 (1.4)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	3 (4.0)	5 (6.6)
Week 2	Number of subjects with Response, n (%)	9 (12.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	0 (0.0)	2 (2.6)
Week 4	Number of subjects with Response, n (%)	24 (31.4)	1 (1.3)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	2 (2.7)	5 (6.6)
Week 8	Number of subjects with Response, n (%)	36 (48.2)	2 (2.8)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	1 (1.3)	7 (9.2)
Week 12	Number of subjects with Response, n (%)	30 (40.3)	3 (3.5)
	Number of imputations (NRI), n (%)	1 (1.3)	8 (10.5)
	Number of imputations (MI), n (%)	1 (1.3)	8 (10.5)
Week 16	Number of subjects with Response, n (%)	34 (45.4)	2 (3.0)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	2 (2.7)	9 (11.8)
	Adjusted Analysis		
	Odds Ratio	27.336	
	95% CI	6.324, 118.169	
	p-value	<.0001	
	Relative Risk	15.286	
	95% CI	3.877, 60.265	
	p-value	<.0001	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.8432	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.3
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 100 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	3 (4.0)	5 (6.6)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	0 (0.0)	2 (2.6)
Week 4	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	2 (2.7)	5 (6.6)
Week 8	Number of subjects with Response, n (%)	7 (9.4)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	1 (1.3)	7 (9.2)
Week 12	Number of subjects with Response, n (%)	14 (18.7)	0 (0.1)
	Number of imputations (NRI), n (%)	1 (1.3)	8 (10.5)
	Number of imputations (MI), n (%)	1 (1.3)	8 (10.5)
Week 16	Number of subjects with Response, n (%)	8 (10.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	2 (2.7)	9 (11.8)
	Adjusted Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	8 (10.8)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	1 (1.3)
	Number of imputations (MI), n (%)	1 (1.3)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	23 (30.4)	1 (1.3)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	2 (2.7)	1 (1.3)
Week 3	Number of subjects with Response, n (%)	30 (39.3)	3 (3.9)
	Number of imputations (NRI), n (%)	0 (0.0)	4 (5.3)
	Number of imputations (MI), n (%)	2 (2.7)	4 (5.3)
Week 4	Number of subjects with Response, n (%)	30 (40.5)	2 (2.6)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (3.9)
	Number of imputations (MI), n (%)	3 (4.0)	6 (7.9)
Week 5	Number of subjects with Response, n (%)	34 (45.6)	8 (10.7)
	Number of imputations (NRI), n (%)	0 (0.0)	4 (5.3)
	Number of imputations (MI), n (%)	3 (4.0)	8 (10.5)
Week 6	Number of subjects with Response, n (%)	33 (43.6)	11 (15.0)
	Number of imputations (NRI), n (%)	0 (0.0)	5 (6.6)
	Number of imputations (MI), n (%)	2 (2.7)	7 (9.2)
Week 7	Number of subjects with Response, n (%)	39 (51.5)	12 (16.1)
	Number of imputations (NRI), n (%)	0 (0.0)	6 (7.9)
	Number of imputations (MI), n (%)	1 (1.3)	8 (10.5)
Week 8	Number of subjects with Response, n (%)	36 (47.5)	15 (19.6)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	2 (2.7)	9 (11.8)
Week 9	Number of subjects with Response, n (%)	34 (44.8)	12 (16.4)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	3 (4.0)	9 (11.8)
Week 10	Number of subjects with Response, n (%)	33 (44.6)	14 (18.9)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	6 (8.0)	8 (10.5)
Week 11	Number of subjects with Response, n (%)	31 (41.8)	13 (17.6)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	7 (9.3)	9 (11.8)
Week 12	Number of subjects with Response, n (%)	32 (42.0)	14 (18.1)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	7 (9.3)	8 (10.5)
Week 13	Number of subjects with Response, n (%)	35 (46.5)	11 (14.1)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	6 (8.0)	10 (13.2)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 14	Number of subjects with Response, n (%)	33 (43.6)	11 (14.8)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	6 (8.0)	10 (13.2)
Week 15	Number of subjects with Response, n (%)	36 (47.6)	11 (14.6)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	7 (9.3)	13 (17.1)
Week 16	Number of subjects with Response, n (%)	35 (46.4)	13 (17.1)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	12 (16.0)	12 (15.8)
	Adjusted Analysis		
	Odds Ratio	4.462	
	95% CI	1.932, 10.305	
	p-value	0.0005	
	Relative Risk	2.613	
	95% CI	1.458, 4.682	
	p-value	0.0013	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.3524	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	1 (1.3)
	Number of imputations (MI), n (%)	1 (1.3)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	2 (2.7)	1 (1.3)
Week 3	Number of subjects with Response, n (%)	2 (2.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	4 (5.3)
	Number of imputations (MI), n (%)	2 (2.7)	4 (5.3)
Week 4	Number of subjects with Response, n (%)	8 (10.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (3.9)
	Number of imputations (MI), n (%)	3 (4.0)	6 (7.9)
Week 5	Number of subjects with Response, n (%)	9 (12.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	4 (5.3)
	Number of imputations (MI), n (%)	3 (4.0)	8 (10.5)
Week 6	Number of subjects with Response, n (%)	9 (12.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	5 (6.6)
	Number of imputations (MI), n (%)	2 (2.7)	7 (9.2)
Week 7	Number of subjects with Response, n (%)	11 (14.7)	2 (2.6)
	Number of imputations (NRI), n (%)	0 (0.0)	6 (7.9)
	Number of imputations (MI), n (%)	1 (1.3)	8 (10.5)
Week 8	Number of subjects with Response, n (%)	12 (16.0)	1 (1.3)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	2 (2.7)	9 (11.8)
Week 9	Number of subjects with Response, n (%)	15 (20.0)	2 (2.6)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	3 (4.0)	9 (11.8)
Week 10	Number of subjects with Response, n (%)	10 (13.3)	3 (3.9)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	6 (8.0)	8 (10.5)
Week 11	Number of subjects with Response, n (%)	8 (10.7)	3 (3.9)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	7 (9.3)	9 (11.8)
Week 12	Number of subjects with Response, n (%)	11 (14.7)	3 (3.9)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	7 (9.3)	8 (10.5)
Week 13	Number of subjects with Response, n (%)	11 (14.7)	2 (2.6)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	6 (8.0)	10 (13.2)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 14	Number of subjects with Response, n (%)	12 (16.0)	1 (1.3)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	6 (8.0)	10 (13.2)
Week 15	Number of subjects with Response, n (%)	15 (20.0)	2 (2.6)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	7 (9.3)	13 (17.1)
Week 16	Number of subjects with Response, n (%)	11 (14.7)	2 (2.6)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	12 (16.0)	12 (15.8)
	Adjusted Analysis		
	Odds Ratio	6.459	
	95% CI	1.374, 30.374	
	p-value	0.0182	
	Relative Risk	5.617	
	95% CI	1.290, 24.454	
	p-value	0.0215	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.0757	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.6
Sensitivity Analysis of Body Surface Area (BSA) = 0 (NRI/MI)
(ITT_M Population)

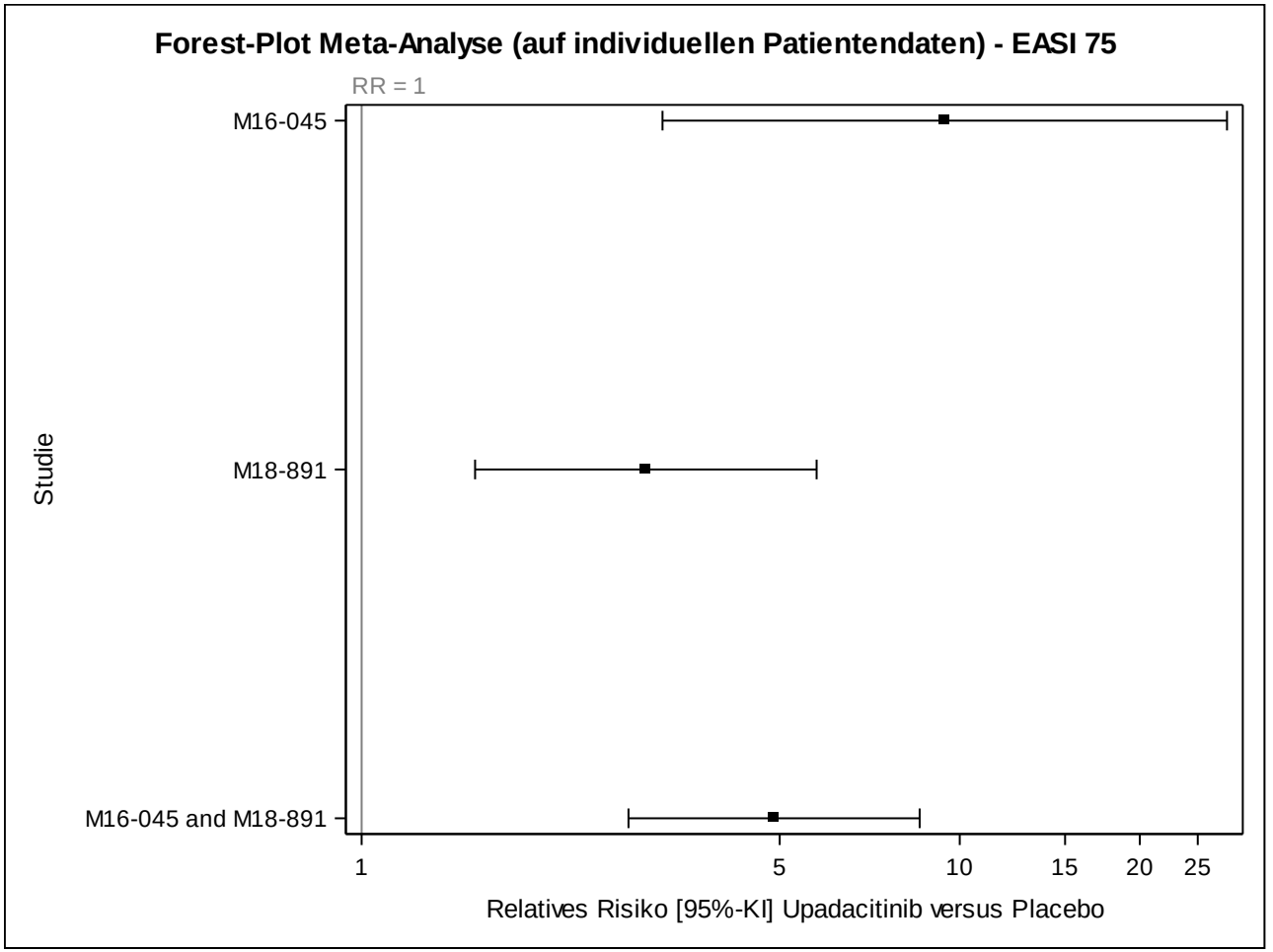
Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	3 (4.0)	5 (6.6)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	0 (0.0)	2 (2.6)
Week 4	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	2 (2.7)	6 (7.9)
Week 8	Number of subjects with Response, n (%)	7 (9.3)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	1 (1.3)	8 (10.5)
Week 12	Number of subjects with Response, n (%)	14 (18.7)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (1.3)	8 (10.5)
	Number of imputations (MI), n (%)	2 (2.7)	8 (10.5)
Week 16	Number of subjects with Response, n (%)	8 (10.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	2 (2.7)	9 (11.8)
	Adjusted Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.7
Sensitivity Analysis of Patient Global Impression of Severity (PGIS) = 0 (NRI/MI)
(ITT_M Population)

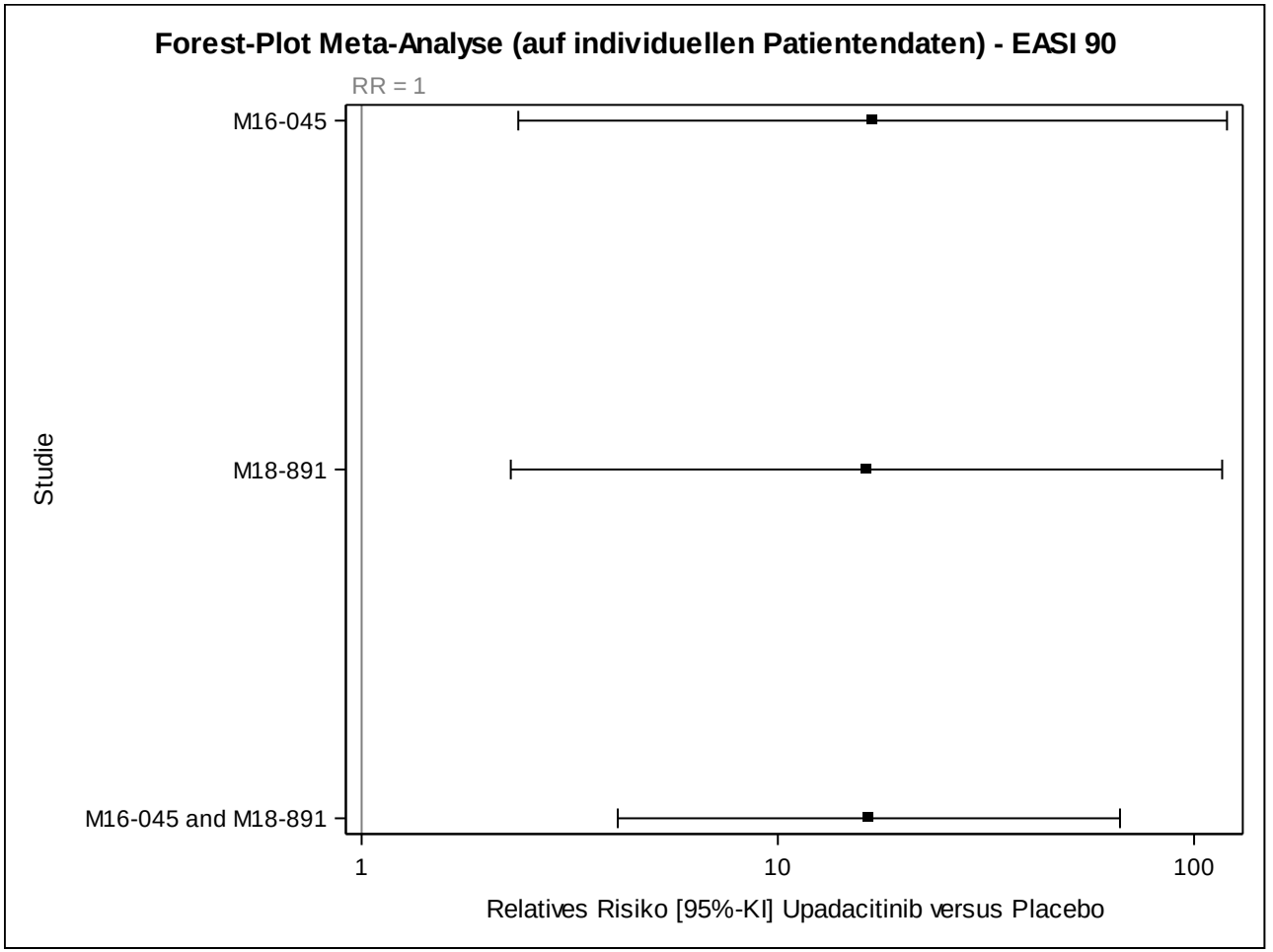
Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 1	Number of subjects with Response, n (%)	3 (4.3)	2 (2.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	4 (5.3)	9 (11.8)
Week 2	Number of subjects with Response, n (%)	4 (5.4)	1 (1.4)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	1 (1.3)	2 (2.6)
Week 4	Number of subjects with Response, n (%)	11 (14.8)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (2.6)
	Number of imputations (MI), n (%)	3 (4.0)	5 (6.6)
Week 12	Number of subjects with Response, n (%)	15 (19.3)	4 (5.4)
	Number of imputations (NRI), n (%)	1 (1.3)	8 (10.5)
	Number of imputations (MI), n (%)	1 (1.3)	10 (13.2)
Week 16	Number of subjects with Response, n (%)	13 (17.8)	5 (6.6)
	Number of imputations (NRI), n (%)	0 (0.0)	8 (10.5)
	Number of imputations (MI), n (%)	2 (2.7)	8 (10.5)
	Adjusted Analysis		
	Odds Ratio	3.159	
	95% CI	1.003, 9.950	
	p-value	0.0495	
	Relative Risk	2.747	
	95% CI	0.978, 7.716	
	p-value	0.0551	
	Risk Difference	0.120	
	95% CI	0.012, 0.229	
	p-value	0.0297	
	Interaction p-value	0.5471	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

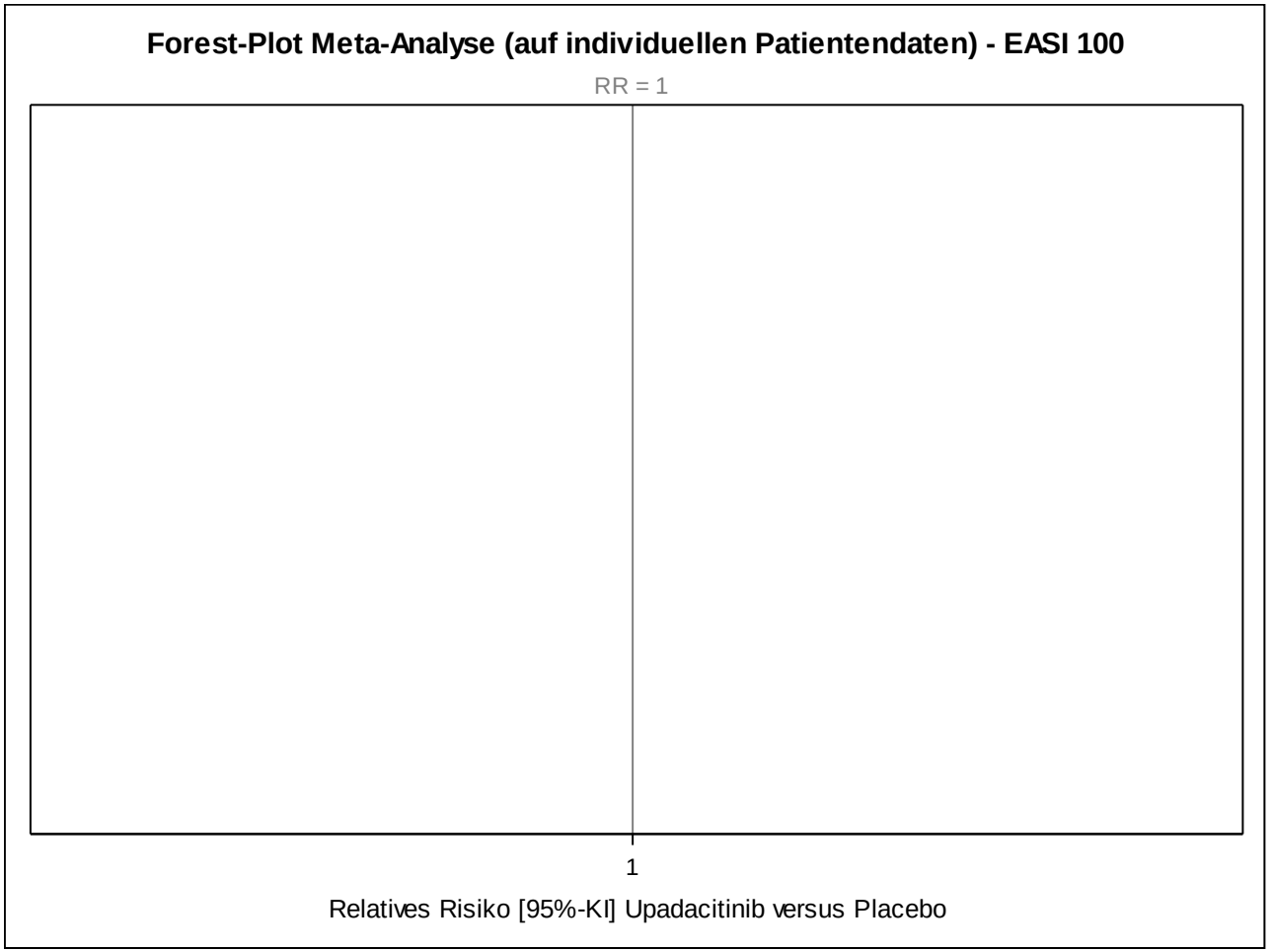


modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

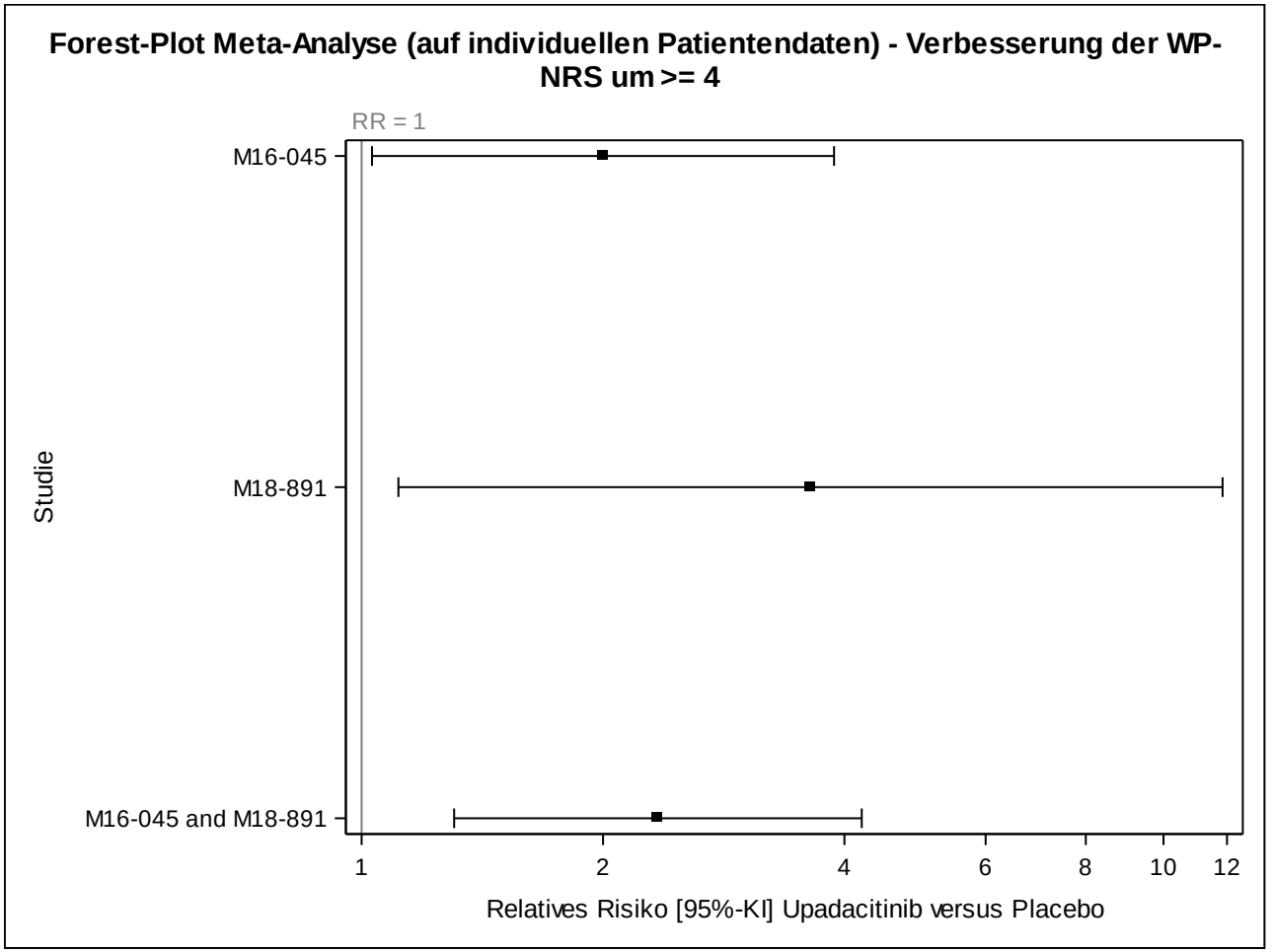
Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Figure 2.5.2
Forest Plot - Eczema Area and Severity Index (EASI) 90 response (modified NRI-C)
(ITT_M Population)



modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.



modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.



modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
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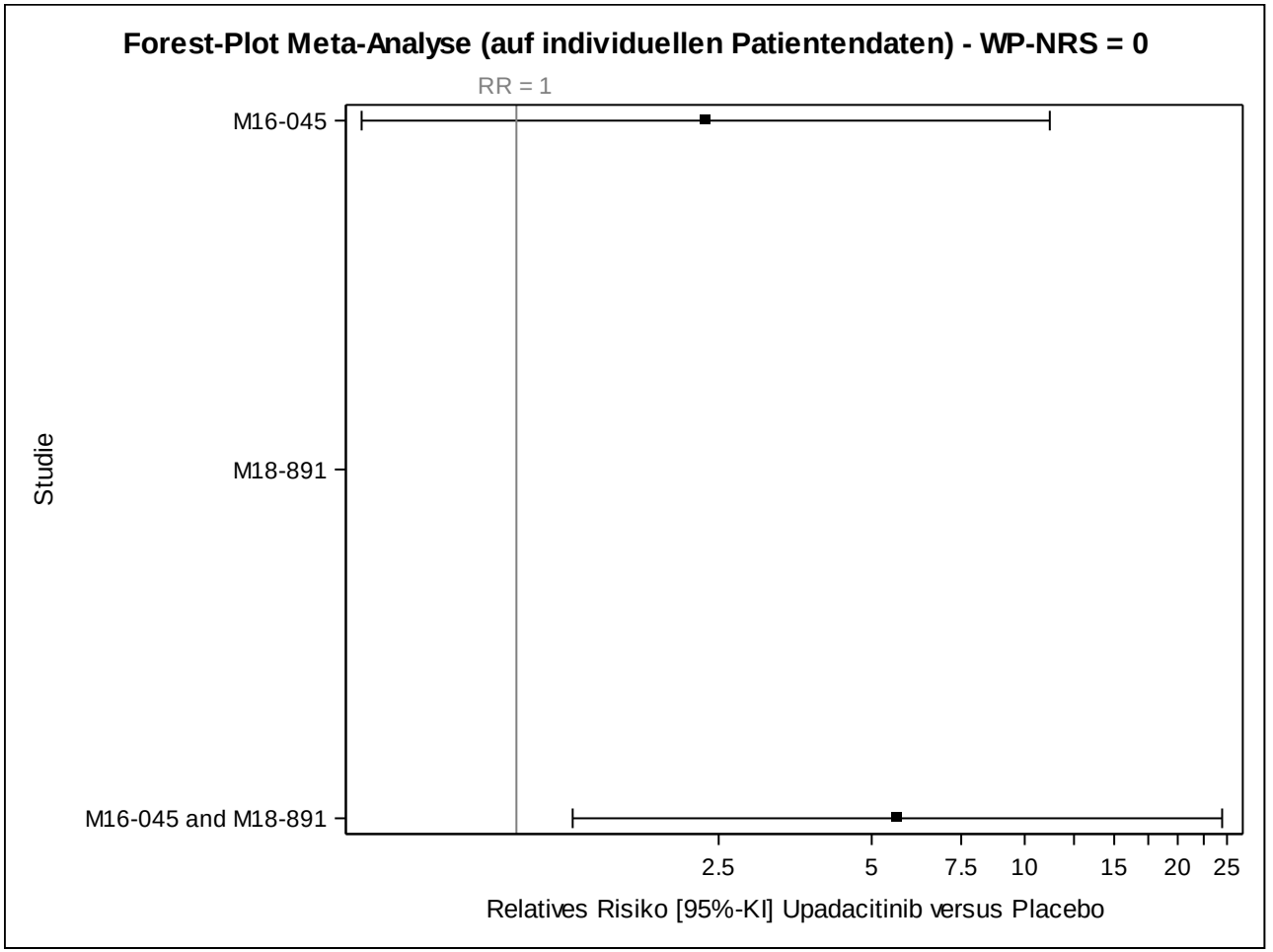
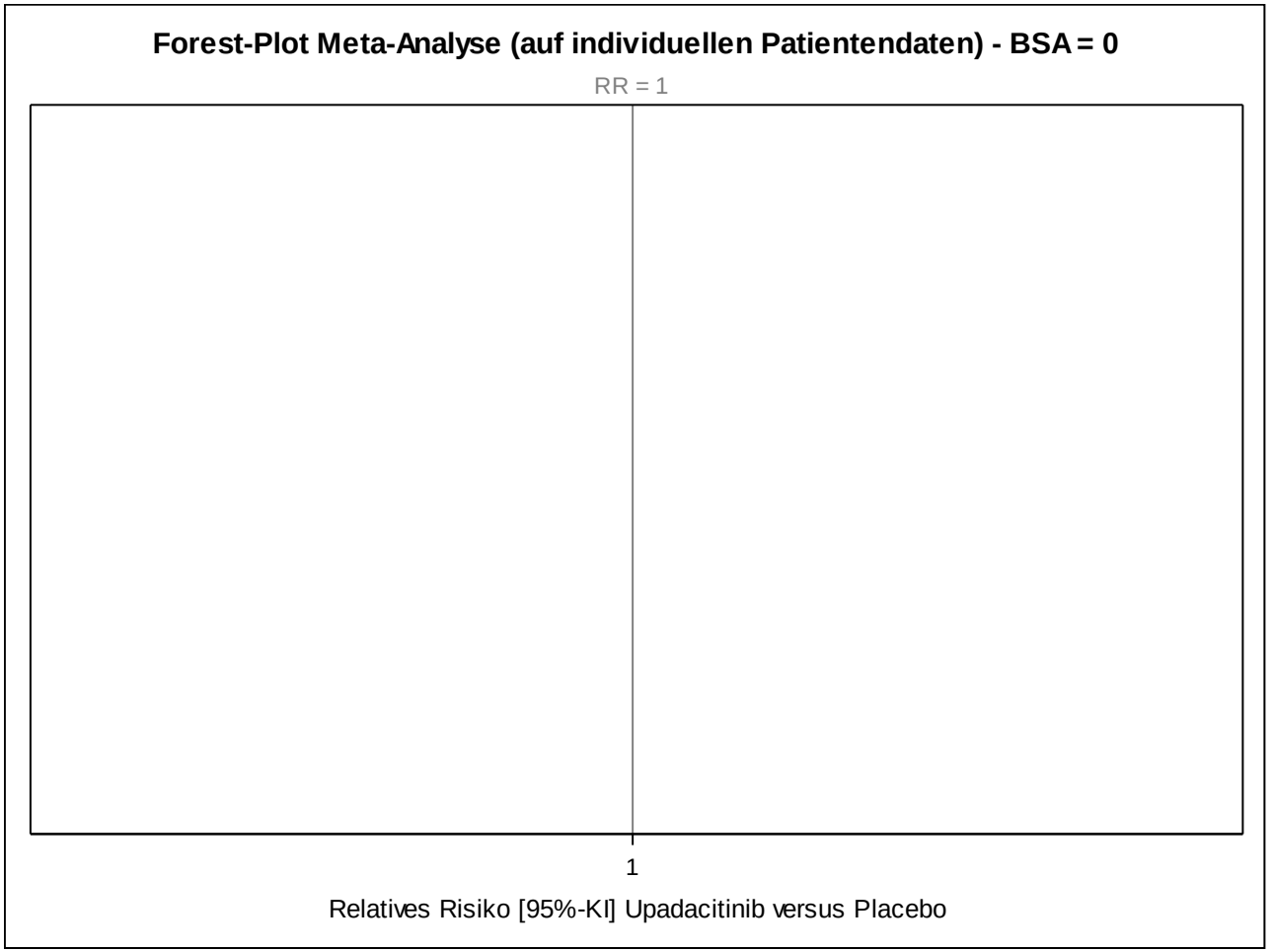
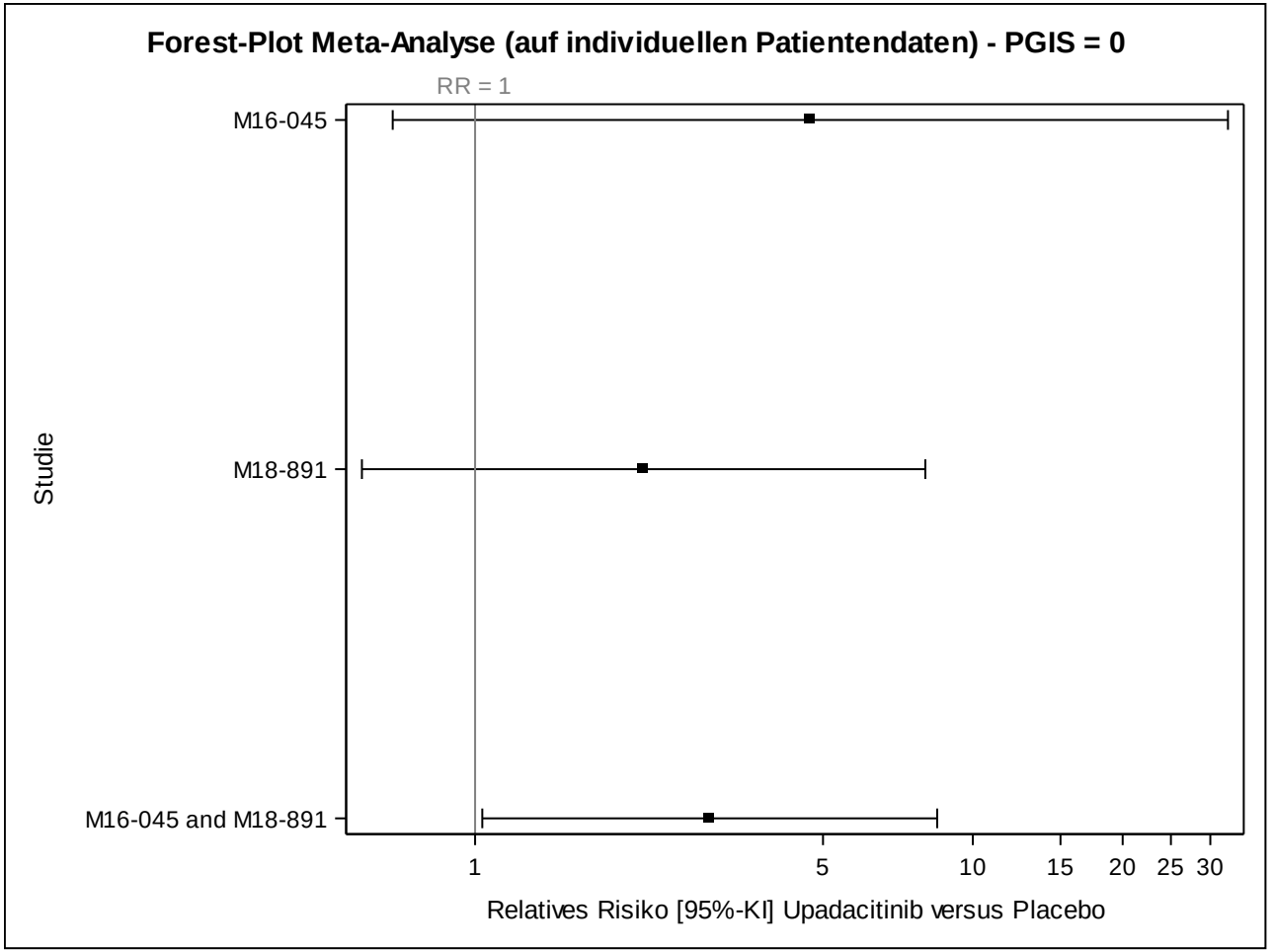
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.



modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.



modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.



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Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.1
Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	47 (62.7)	36 (47.4)
	Unstratified Analysis		
	Odds Ratio	1.875	
	95% CI	0.979, 3.594	
	p-value	0.0581	
	Relative Risk	1.324	
	95% CI	0.986, 1.776	
	p-value	0.0616	
	Risk Difference	0.154	
	95% CI	-0.003, 0.311	
	p-value	0.0541	
	Interaction p-value	0.7957	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.2
Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	47 (62.7)	30 (39.5)
	Unstratified Analysis		
	Odds Ratio	2.567	
	95% CI	1.331, 4.948	
	p-value	0.0049	
	Relative Risk	1.584	
	95% CI	1.139, 2.203	
	p-value	0.0062	
	Risk Difference	0.231	
	95% CI	0.076, 0.386	
	p-value	0.0035	
	Interaction p-value	0.5730	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.3
Serious Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	3 (4.0)	3 (3.9)
	Unstratified Analysis		
	Odds Ratio	1.045	
	95% CI	0.203, 5.386	
	p-value	0.9582	
	Relative Risk	1.044	
	95% CI	0.219, 4.982	
	p-value	0.9572	
	Risk Difference	0.000	
	95% CI	-0.057, 0.058	
	p-value	0.9868	
	Interaction p-value	0.9364	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.4
Serious Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	3 (4.0)	1 (1.3)
	Unstratified Analysis		
	Odds Ratio	3.295	
	95% CI	0.331, 32.750	
	p-value	0.3089	
	Relative Risk	3.142	
	95% CI	0.337, 29.293	
	p-value	0.3148	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.4310	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.5
Adverse Events of CTCAE Grade >=3
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	6 (8.0)	3 (3.9)
	Unstratified Analysis		
	Odds Ratio	2.085	
	95% CI	0.500, 8.688	
	p-value	0.3129	
	Relative Risk	2.019	
	95% CI	0.525, 7.760	
	p-value	0.3064	
	Risk Difference	0.034	
	95% CI	-0.053, 0.122	
	p-value	0.4413	
	Interaction p-value	0.1505	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.6
Adverse Events of CTCAE Grade >=3 (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	6 (8.0)	1 (1.3)
	Unstratified Analysis		
	Odds Ratio	6.422	
	95% CI	0.752, 54.854	
	p-value	0.0893	
	Relative Risk	6.019	
	95% CI	0.744, 48.676	
	p-value	0.0924	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.0925	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.7
Adverse Events of CTCAE Grade <3
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	47 (62.7)	36 (47.4)
	Unstratified Analysis		
	Odds Ratio	1.875	
	95% CI	0.979, 3.594	
	p-value	0.0581	
	Relative Risk	1.324	
	95% CI	0.986, 1.776	
	p-value	0.0616	
	Risk Difference	0.154	
	95% CI	-0.003, 0.311	
	p-value	0.0541	
	Interaction p-value	0.7957	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.8
Adverse Events leading to discontinuation of study drug
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	2 (2.7)	2 (2.6)
	Unstratified Analysis		
	Odds Ratio	1.057	
	95% CI	0.143, 7.782	
	p-value	0.9569	
	Relative Risk	1.072	
	95% CI	0.156, 7.360	
	p-value	0.9433	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.1686	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.9
Fatal Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.1
Adverse Events of Special Interest - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	1 (1.3)	1 (1.3)
	Unstratified Analysis		
	Odds Ratio	1.020	
	95% CI	0.062, 16.634	
	p-value	0.9892	
	Relative Risk	1.017	
	95% CI	0.065, 15.970	
	p-value	0.9904	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.1026	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.2
Adverse Events of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.3
Adverse Events of Special Interest - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	1 (1.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.4
Adverse Events of Special Interest - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.5
Adverse Events of Special Interest - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.6
Adverse Events of Special Interest - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.7
Adverse Events of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.8
Adverse Events of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.9
Adverse Events of Special Interest - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.10
Adverse Events of Special Interest - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	3 (4.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.11
Adverse Events of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.12
Adverse Events of Special Interest - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	1 (1.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.13
Adverse Events of Special Interest - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	2 (2.7)	1 (1.3)
	Unstratified Analysis		
	Odds Ratio	2.123	
	95% CI	0.187, 24.057	
	p-value	0.5433	
	Relative Risk	2.122	
	95% CI	0.197, 22.861	
	p-value	0.5351	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.0441	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.14
Adverse Events of Special Interest - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.15
Adverse Events of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	5 (6.7)	3 (3.9)
	Unstratified Analysis		
	Odds Ratio	1.696	
	95% CI	0.388, 7.416	
	p-value	0.4827	
	Relative Risk	1.650	
	95% CI	0.411, 6.622	
	p-value	0.4798	
	Risk Difference	0.018	
	95% CI	-0.052, 0.087	
	p-value	0.6170	
	Interaction p-value	0.7319	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.16
Adverse Events of Special Interest - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.17
Adverse Events of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.18
Adverse Events of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.1
Serious Adverse Event of Special Interest - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	1 (1.3)	1 (1.3)
	Unstratified Analysis		
	Odds Ratio	1.020	
	95% CI	0.062, 16.634	
	p-value	0.9892	
	Relative Risk	1.017	
	95% CI	0.065, 15.970	
	p-value	0.9904	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.1026	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.2
Serious Adverse Event of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.3
Serious Adverse Event of Special Interest - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.4
Serious Adverse Event of Special Interest - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.5
Serious Adverse Event of Special Interest - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.6
Serious Adverse Event of Special Interest - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.7
Serious Adverse Event of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.8
Serious Adverse Event of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.9
Serious Adverse Event of Special Interest - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.10
Serious Adverse Event of Special Interest - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.11
Serious Adverse Event of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.12
Serious Adverse Event of Special Interest - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.13
Serious Adverse Event of Special Interest - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.14
Serious Adverse Event of Special Interest - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.15
Serious Adverse Event of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.16
Serious Adverse Event of Special Interest - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.17
Serious Adverse Event of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.18
Serious Adverse Event of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.1
Adverse Events of Special Interest of CTCAE Grade >=3 - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	1 (1.3)	1 (1.3)
	Unstratified Analysis		
	Odds Ratio	1.020	
	95% CI	0.062, 16.634	
	p-value	0.9892	
	Relative Risk	1.017	
	95% CI	0.065, 15.970	
	p-value	0.9904	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.1026	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.2
Adverse Events of Special Interest of CTCAE Grade >=3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.3
Adverse Events of Special Interest of CTCAE Grade >=3 - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.4
Adverse Events of Special Interest of CTCAE Grade >=3 - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.5
Adverse Events of Special Interest of CTCAE Grade >=3 - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.6
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.7
Adverse Events of Special Interest of CTCAE Grade >=3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.8
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.9
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.10
Adverse Events of Special Interest of CTCAE Grade >=3 - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.11
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.12
Adverse Events of Special Interest of CTCAE Grade >=3 - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.13
Adverse Events of Special Interest of CTCAE Grade >=3 - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.14
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.15
Adverse Events of Special Interest of CTCAE Grade >=3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	1 (1.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.16
Adverse Events of Special Interest of CTCAE Grade >=3 - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.17
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.18
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.1
Adverse Events of Special Interest of CTCAE Grade <3 - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.2
Adverse Events of Special Interest of CTCAE Grade <3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.3
Adverse Events of Special Interest of CTCAE Grade <3 - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	1 (1.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.4
Adverse Events of Special Interest of CTCAE Grade <3 - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.5
Adverse Events of Special Interest of CTCAE Grade <3 - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.6
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.7
Adverse Events of Special Interest of CTCAE Grade <3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.8
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.9
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.10
Adverse Events of Special Interest of CTCAE Grade <3 - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	3 (4.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.11
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.12
Adverse Events of Special Interest of CTCAE Grade <3 - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	1 (1.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.13
Adverse Events of Special Interest of CTCAE Grade <3 - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	2 (2.7)	1 (1.3)
	Unstratified Analysis		
	Odds Ratio	2.123	
	95% CI	0.187, 24.057	
	p-value	0.5433	
	Relative Risk	2.122	
	95% CI	0.197, 22.861	
	p-value	0.5351	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.0441	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.14
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.15
Adverse Events of Special Interest of CTCAE Grade <3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	5 (6.7)	3 (3.9)
	Unstratified Analysis		
	Odds Ratio	1.696	
	95% CI	0.388, 7.416	
	p-value	0.4827	
	Relative Risk	1.650	
	95% CI	0.411, 6.622	
	p-value	0.4798	
	Risk Difference	0.018	
	95% CI	-0.052, 0.087	
	p-value	0.6170	
	Interaction p-value	0.7319	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.16
Adverse Events of Special Interest of CTCAE Grade <3 - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.17
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.18
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.2.1
Incidence of Adverse Events leading to discontinuation of study drug by SOC and PT
(Safety Analysis Set)

Up to Visit	System Organ Class (SOC) Preferred Term (PT)	Upadacitinib (N=75) n (%)	Placebo (N=76) n (%)
Week 16	Skin and subcutaneous tissue disorders	1 (1.3)	1 (1.3)
	Dermatitis atopic	0 (0.0)	1 (1.3)
	Pruritus	1 (1.3)	0 (0.0)
	Immune system disorders	0 (0.0)	1 (1.3)
	Drug hypersensitivity	0 (0.0)	1 (1.3)
	Respiratory, thoracic and mediastinal disorders	1 (1.3)	0 (0.0)
	Asthma	1 (1.3)	0 (0.0)

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.1 coding dictionary applied.
N: Number of subjects, n: Number of subjects with event
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
SOC: Infections and infestations	Week 16	Number of subjects with events, n (%)	29 (38.7)	16 (21.1)
		Unstratified Analysis		
		Odds Ratio	2.372	
		95% CI	1.152, 4.882	
		p-value	0.0190	
		Relative Risk	1.846	
		95% CI	1.096, 3.107	
		p-value	0.0211	
		Risk Difference	0.176	
		95% CI	0.033, 0.319	
		p-value	0.0161	
		Interaction p-value	0.5501	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
SOC: Infections and infestations - PT:Upper respiratory tract infection	Week 16	Number of subjects with events, n (%)	11 (14.7)	4 (5.3)
		Unstratified Analysis		
		Odds Ratio	3.103	
		95% CI	0.940, 10.236	
		p-value	0.0630	
		Relative Risk	2.804	
		95% CI	0.933, 8.425	
		p-value	0.0663	
		Risk Difference	0.098	
		95% CI	0.003, 0.193	
		p-value	0.0432	
		Interaction p-value	0.2321	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
SOC: Investigations	Week 16	Number of subjects with events, n (%)	9 (12.0)	5 (6.6)
		Unstratified Analysis		
		Odds Ratio	1.902	
		95% CI	0.602, 6.006	
		p-value	0.2731	
		Relative Risk	1.766	
		95% CI	0.623, 5.002	
		p-value	0.2844	
		Risk Difference	0.055	
		95% CI	-0.031, 0.14	
		p-value	0.2076	
		Interaction p-value	0.5024	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
SOC: Respiratory, thoracic and mediastinal disorders	Week 16	Number of subjects with events, n (%)	13 (17.3)	3 (3.9)
		Unstratified Analysis		
		Odds Ratio	5.753	
		95% CI	1.527, 21.677	
		p-value	0.0097	
		Relative Risk	4.624	
		95% CI	1.397, 15.308	
		p-value	0.0122	
		Risk Difference	0.102	
		95% CI	-0.001, 0.20	
		p-value	0.0511	
		Interaction p-value	0.6411	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
SOC: Skin and subcutaneous tissue disorders	Week 16	Number of subjects with events, n (%)	15 (20.0)	14 (18.4)
		Unstratified Analysis		
		Odds Ratio	1.119	
		95% CI	0.497, 2.521	
		p-value	0.7861	
		Relative Risk	1.090	
		95% CI	0.567, 2.095	
		p-value	0.7956	
		Risk Difference	0.020	
		95% CI	-0.105, 0.14	
		p-value	0.7569	
		Interaction p-value	0.6704	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
SOC: Skin and subcutaneous tissue disorders - PT:Acne	Week 16	Number of subjects with events, n (%)	10 (13.3)	1 (1.3)
		Unstratified Analysis		
		Odds Ratio	11.560	
		95% CI	1.440, 92.795	
		p-value	0.0213	
		Relative Risk	10.138	
		95% CI	1.330, 77.255	
		p-value	0.0254	
		Risk Difference	NE	
		95% CI	NE, NE	
		p-value	NE	
		Interaction p-value	0.2083	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=75)	Placebo (N=76)
SOC: Skin and subcutaneous tissue disorders - PT:Dermatitis atopic	Week 16	Number of subjects with events, n (%)	2 (2.7)	9 (11.8)
		Unstratified Analysis		
		Odds Ratio	0.206	
		95% CI	0.042, 0.998	
		p-value	0.0497	
		Relative Risk	0.231	
		95% CI	0.052, 1.023	
		p-value	0.0535	
		Risk Difference	-0.070	
		95% CI	-0.162, 0.02	
		p-value	0.1337	
		Interaction p-value	0.4862	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.2
Frequent Serious Adverse Events by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

!!! There are no Observations for this Report !!!

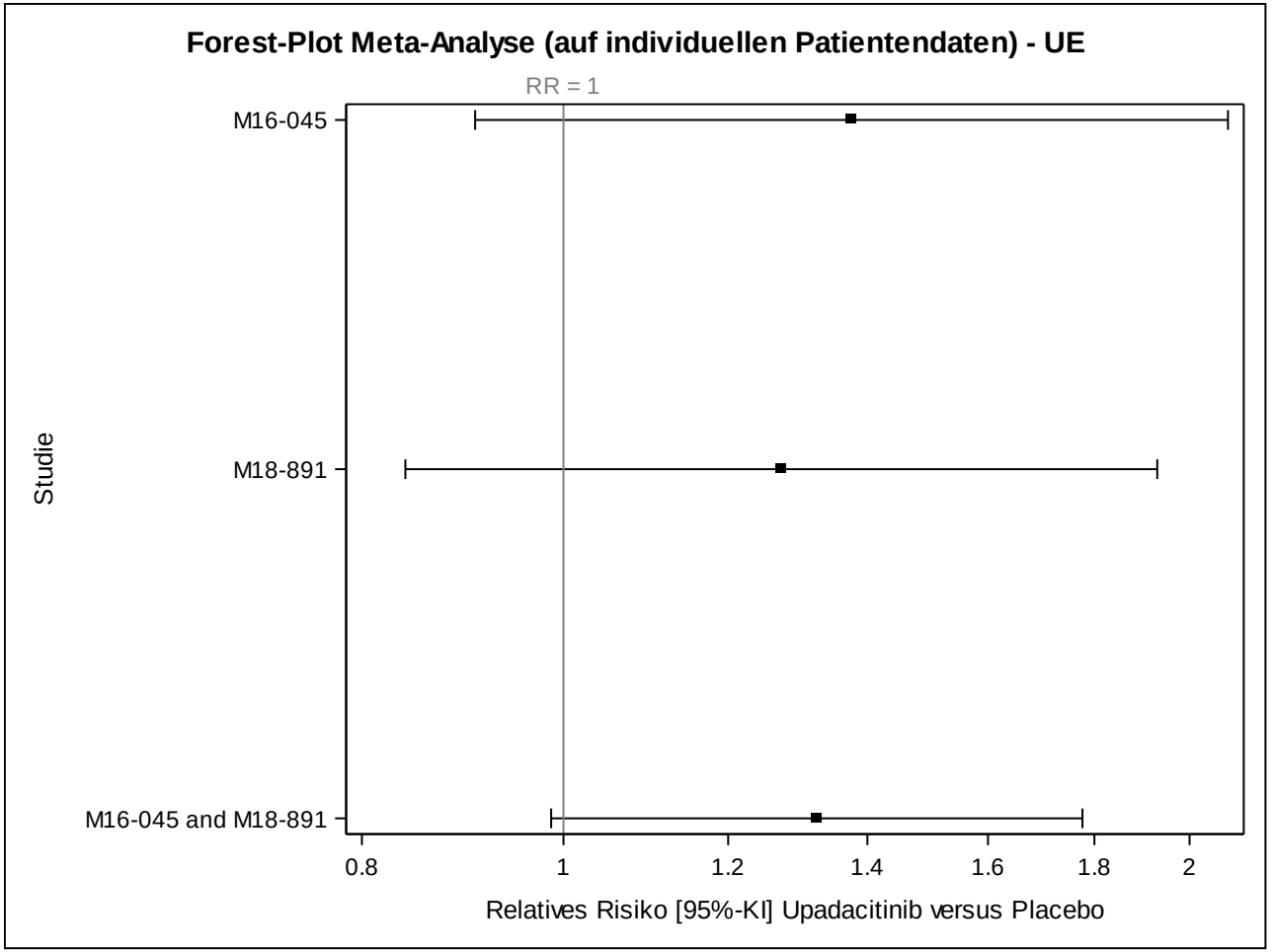
Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.3
Frequent Adverse Events of CTCAE Grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

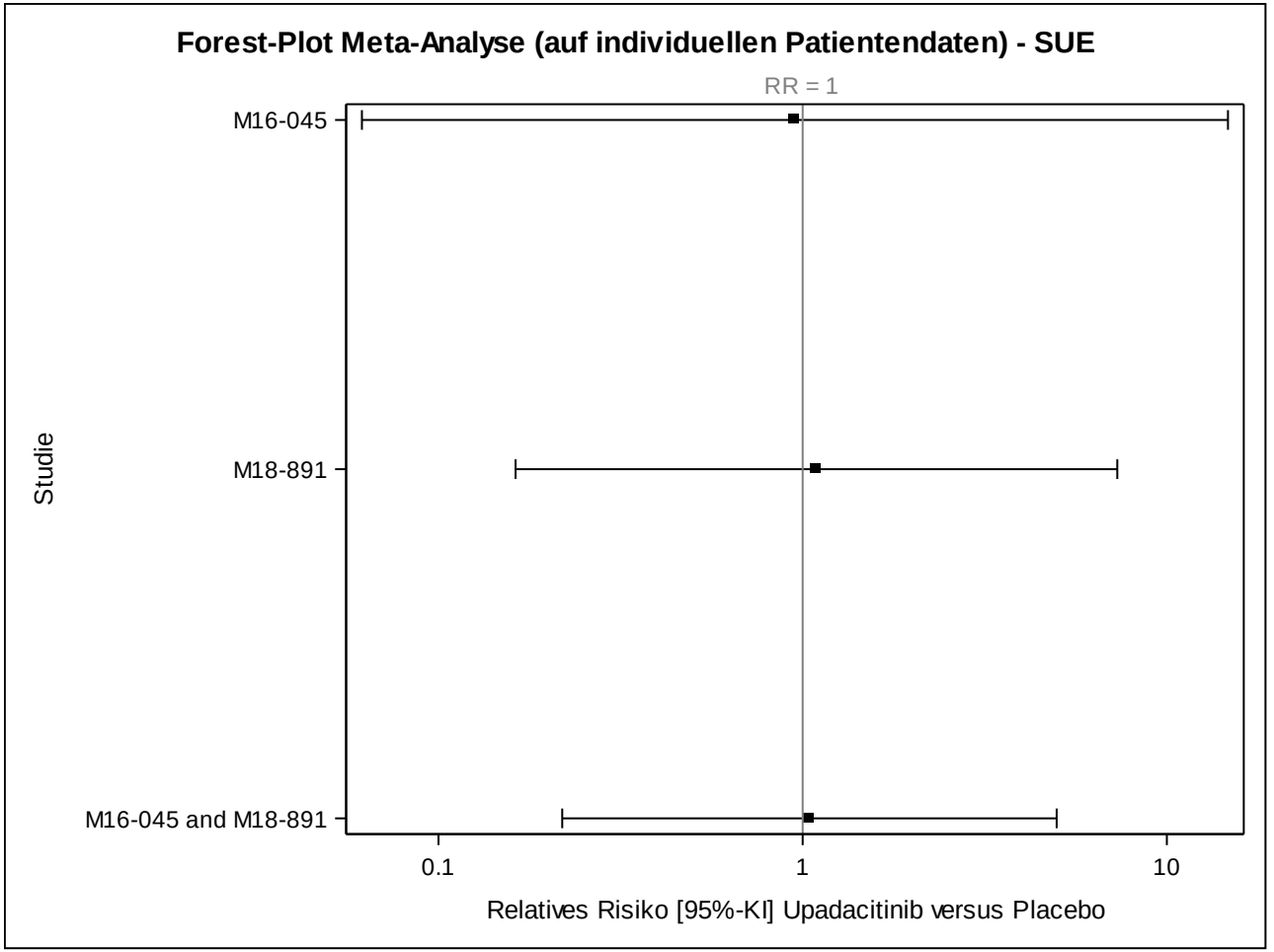
!!! There are no Observations for this Report !!!

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

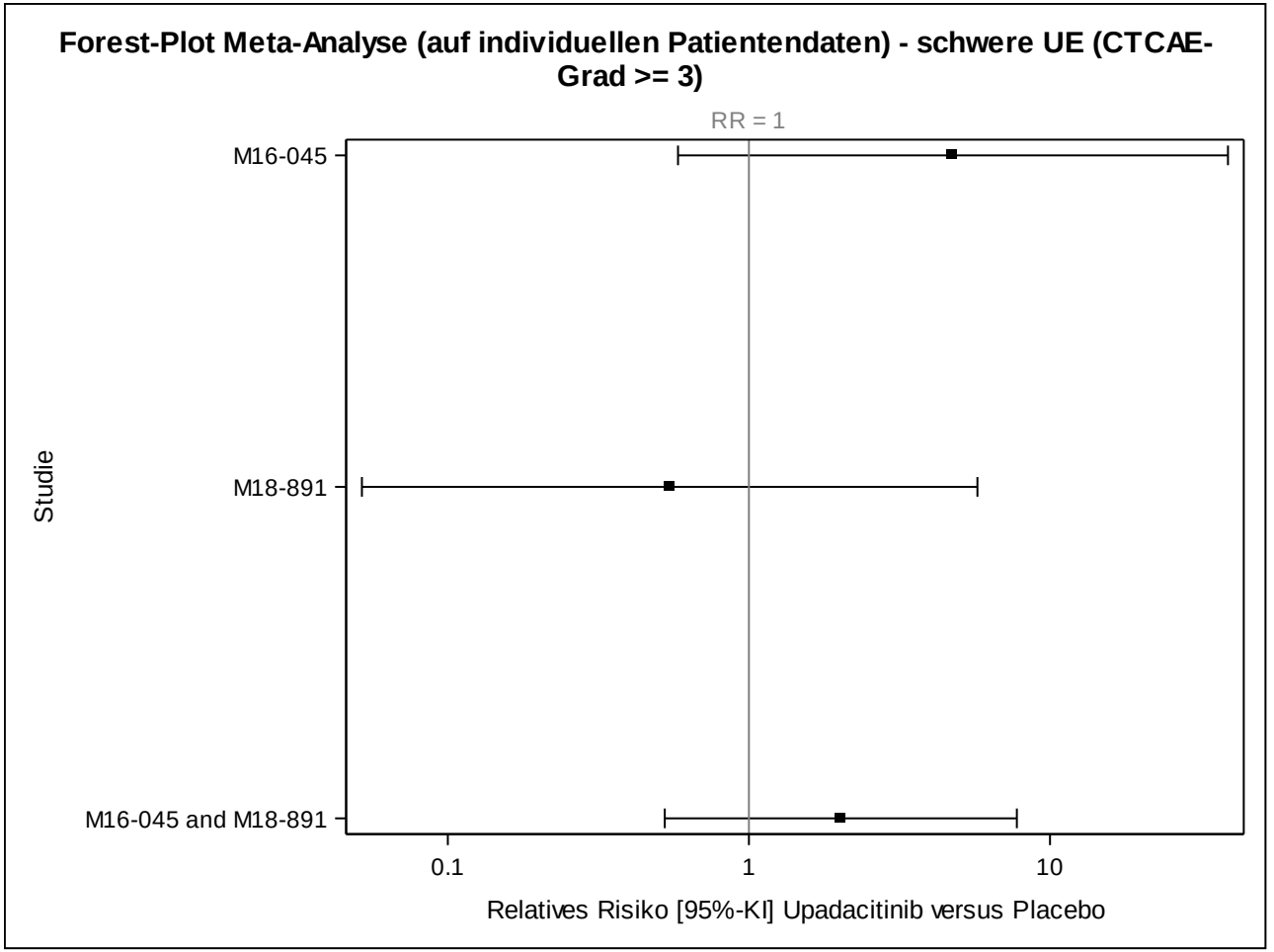
Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Figure 3.4.1.1
Forest Plot - Adverse Events
(ITT_M Population)



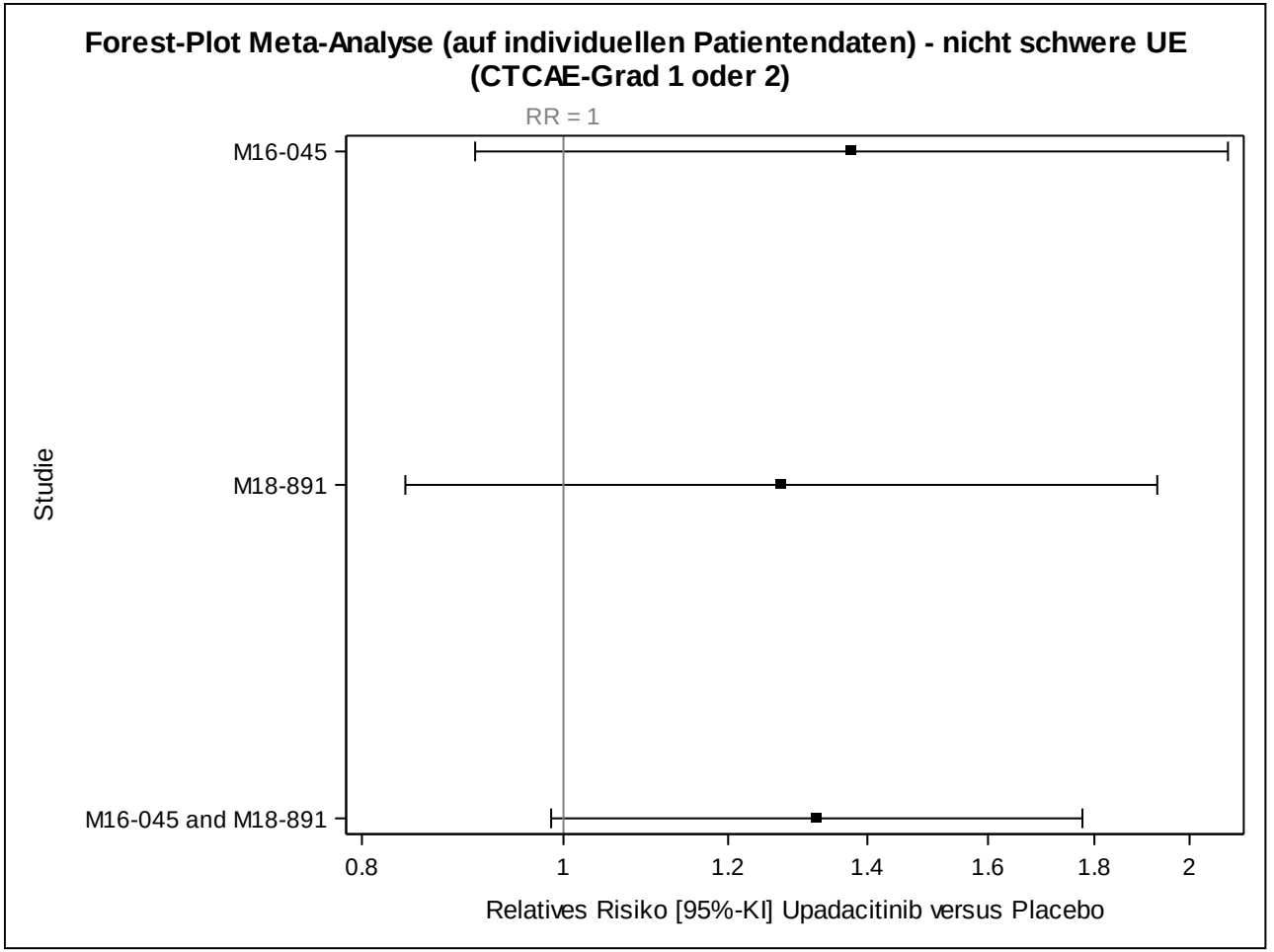
Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.



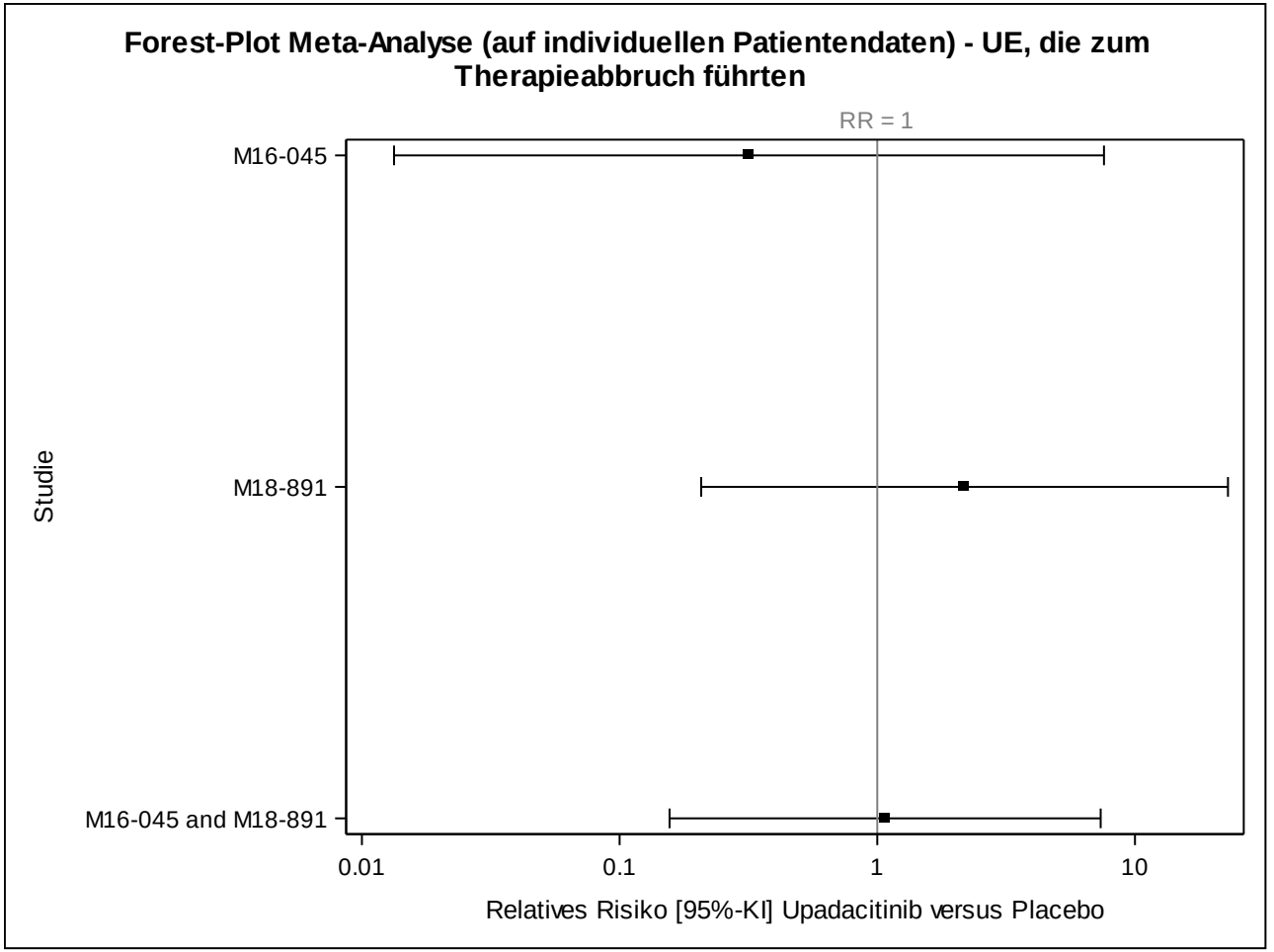
Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.



Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

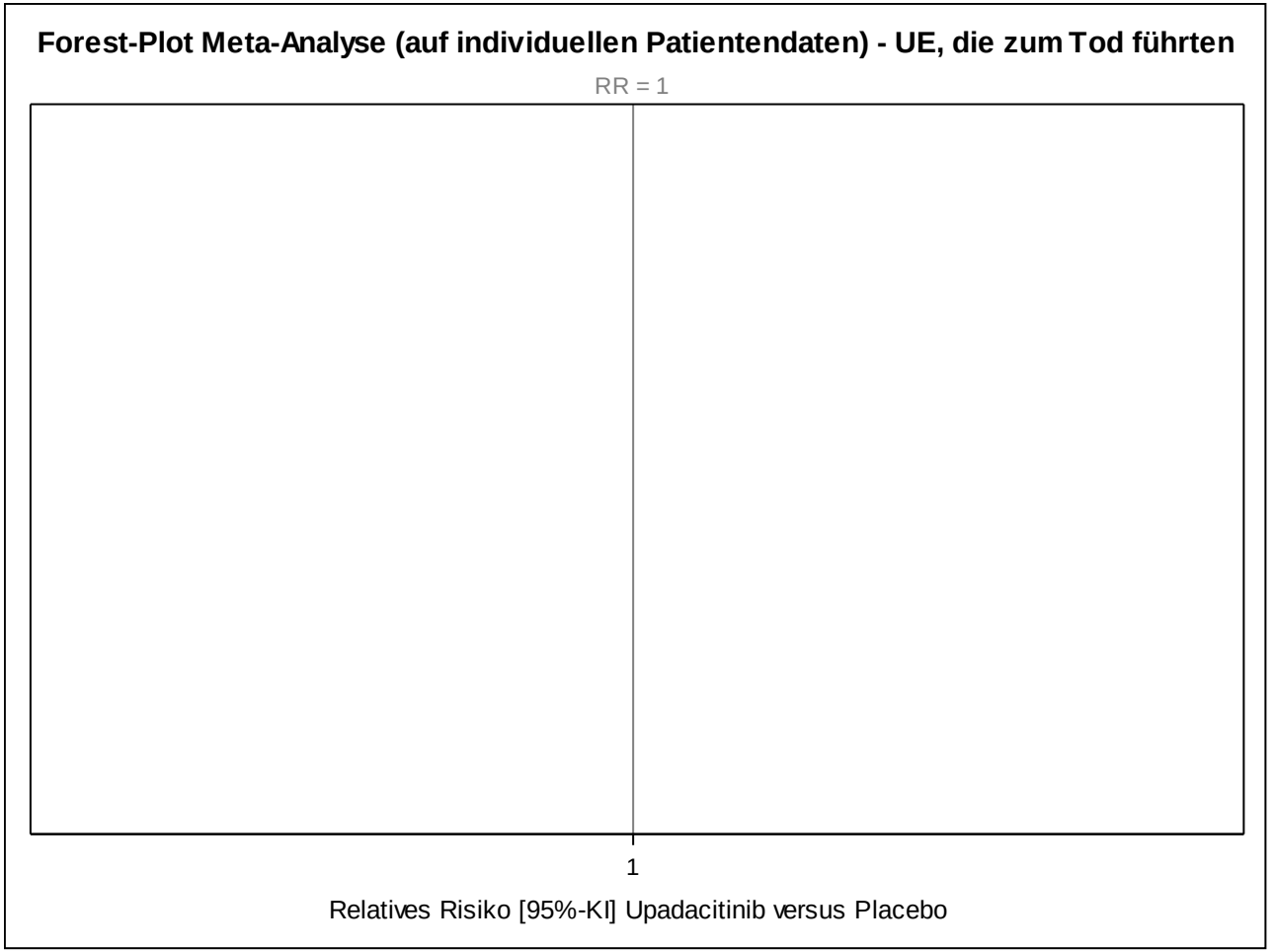


Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.



Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Figure 3.4.6.1
Forest Plot - Fatal Adverse Events
(ITT_M Population)



Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg treatment group.

		Upadacitinib (N=972)	Placebo (N=483)	Total (N=1455)
Age (years)	n (missing)	972 (0)	483 (0)	1455 (0)
	Mean (SD)	36.62 (15.10)	36.79 (14.27)	36.67 (14.82)
	Median	32.00	33.00	32.00
	Q1, Q3	24.00, 48.00	25.00, 47.00	24.00, 48.00
	Min, Max	18.00, 75.00	18.00, 75.00	18.00, 75.00
Age Group (years) - n (%)	< 18	0 (0.0)	0 (0.0)	0 (0.0)
	18 - < 40	623 (64.1)	306 (63.4)	929 (63.8)
	40 - < 65	287 (29.5)	155 (32.1)	442 (30.4)
	>=65	62 (6.4)	22 (4.6)	84 (5.8)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Sex - n (%)	Female	418 (43.0)	218 (45.1)	636 (43.7)
	Male	554 (57.0)	265 (54.9)	819 (56.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Race - n (%)	White	648 (66.7)	322 (66.7)	970 (66.7)
	Black	60 (6.2)	31 (6.4)	91 (6.3)
	Asian	235 (24.2)	114 (23.6)	349 (24.0)
	Other	29 (3.0)	16 (3.3)	45 (3.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Geographic Region - n (%)	US/PR/Canada	409 (42.1)	203 (42.0)	612 (42.1)
	Other	563 (57.9)	280 (58.0)	843 (57.9)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Weight (kg)	n (missing)	972 (0)	482 (1)	1454 (1)
	Mean (SD)	76.12 (18.45)	77.87 (19.69)	76.70 (18.88)
	Median	73.05	75.00	74.05
	Q1, Q3	62.75, 86.15	64.10, 88.50	63.50, 86.90
	Min, Max	36.30, 160.60	38.30, 175.00	36.30, 175.00
Weight (kg) (Median M16-045: 71 , M18-891: 72.94) - n (%)	< Median	460 (47.3)	203 (42.1)	663 (45.6)
	>= Median	512 (52.7)	279 (57.9)	791 (54.4)
	Missing	0 (0.0)	1 (0.2)	1 (0.1)
Body Mass Index (kg/m^2)	n (missing)	969 (3)	477 (6)	1446 (9)
	Mean (SD)	26.30 (5.86)	26.91 (6.01)	26.50 (5.92)
	Median	25.10	25.60	25.30
	Q1, Q3	22.10, 29.10	22.70, 30.00	22.40, 29.40
	Min, Max	15.40, 55.70	16.00, 52.90	15.40, 55.70
Body Mass Index (kg/m^2) - n (%)	< 25	467 (48.2)	200 (41.9)	667 (46.1)
	25 - < 30	302 (31.2)	157 (32.9)	459 (31.7)
	>= 30	200 (20.6)	120 (25.2)	320 (22.1)
	Missing	3 (0.3)	6 (1.3)	9 (0.6)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.1
Demographic and Baseline Characteristics
(ITT_M Population)

		Upadacitinib (N=972)	Placebo (N=483)	Total (N=1455)
Baseline EASI	n (missing)	972 (0)	482 (1)	1454 (1)
	Mean (SD)	29.41 (11.90)	28.56 (11.96)	29.13 (11.93)
	Median	26.40	24.65	25.80
	Q1, Q3	19.60, 35.30	19.50, 33.50	19.60, 34.90
	Min, Max	16.00, 70.30	16.00, 72.00	16.00, 72.00
Baseline EASI - n (%)	< Median (25.8)	465 (47.8)	260 (53.9)	725 (49.9)
	>= Median (25.8)	507 (52.2)	222 (46.1)	729 (50.1)
	Missing	0 (0.0)	1 (0.2)	1 (0.1)
Baseline vIGA-AD	n (missing)	972 (0)	483 (0)	1455 (0)
	Mean (SD)	3.51 (0.50)	3.50 (0.50)	3.50 (0.50)
	Median	4.00	3.00	4.00
	Q1, Q3	3.00, 4.00	3.00, 4.00	3.00, 4.00
	Min, Max	3.00, 4.00	3.00, 4.00	3.00, 4.00
Baseline vIGA-AD - n (%)	3 (Moderate)	481 (49.5)	242 (50.1)	723 (49.7)
	4 (Severe)	491 (50.5)	241 (49.9)	732 (50.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline hsCRP	n (missing)	972 (0)	483 (0)	1455 (0)
	Mean (SD)	3.88 (7.01)	4.28 (6.78)	4.01 (6.93)
	Median	1.64	1.85	1.67
	Q1, Q3	0.62, 4.32	0.77, 4.74	0.67, 4.47
	Min, Max	0.20, 80.20	0.20, 57.60	0.20, 80.20
Baseline hsCRP (Median M16-045: 1.4 , M18-891: 1.645) - n (%)	< Median	459 (47.2)	215 (44.5)	674 (46.3)
	>= Median	513 (52.8)	268 (55.5)	781 (53.7)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Topical Therapy - n (%)	With	938 (96.5)	456 (94.4)	1394 (95.8)
	Without	34 (3.5)	27 (5.6)	61 (4.2)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Systemic Therapy - n (%)	With	491 (50.5)	266 (55.1)	757 (52.0)
	Without	481 (49.5)	217 (44.9)	698 (48.0)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Phototherapy - n (%)	With	173 (17.8)	84 (17.4)	257 (17.7)
	Without	799 (82.2)	399 (82.6)	1198 (82.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline BSA	n (missing)	972 (0)	482 (1)	1454 (1)
	Mean (SD)	46.75 (22.39)	45.98 (21.99)	46.50 (22.25)
	Median	43.00	42.00	42.25
	Q1, Q3	29.00, 63.00	29.00, 60.00	29.00, 62.00
	Min, Max	10.00, 99.00	11.00, 99.90	10.00, 99.90

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.1
Demographic and Baseline Characteristics
(ITT_M Population)

		Upadacitinib (N=972)	Placebo (N=483)	Total (N=1455)
Worst Pruritus NRS (Weekly Average)	n (missing)	966 (6)	477 (6)	1443 (12)
	Mean (SD)	7.26 (1.53)	7.32 (1.60)	7.28 (1.55)
	Median	7.29	7.43	7.33
	Q1, Q3	6.17, 8.29	6.29, 8.43	6.20, 8.40
	Min, Max	2.14, 10.00	0.29, 10.00	0.29, 10.00
Baseline PGIS	n (missing)	954 (18)	476 (7)	1430 (25)
	Mean (SD)	4.43 (1.09)	4.51 (1.08)	4.46 (1.09)
	Median	4.00	5.00	5.00
	Q1, Q3	4.00, 5.00	4.00, 5.00	4.00, 5.00
	Min, Max	0.00, 6.00	1.00, 6.00	0.00, 6.00
Disease duration since diagnosis (years)	n (missing)	971 (1)	483 (0)	1454 (1)
	Mean (SD)	21.34 (15.12)	22.48 (15.02)	21.72 (15.09)
	Median	19.89	21.35	20.47
	Q1, Q3	8.16, 29.46	9.96, 30.97	8.73, 30.14
	Min, Max	0.05, 74.28	0.04, 69.47	0.04, 74.28
Any Allergic Comorbidity - n (%)	With	676 (69.5)	346 (71.6)	1022 (70.2)
	Without	296 (30.5)	137 (28.4)	433 (29.8)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Food Allergy - n (%)	With	331 (34.1)	144 (29.8)	475 (32.6)
	Without	641 (65.9)	339 (70.2)	980 (67.4)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Asthma - n (%)	With	388 (39.9)	201 (41.6)	589 (40.5)
	Without	584 (60.1)	282 (58.4)	866 (59.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Allergic Rhinitis - n (%)	With	471 (48.5)	227 (47.0)	698 (48.0)
	Without	501 (51.5)	256 (53.0)	757 (52.0)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Eosinophilic Esophagitis - n (%)	With	3 (0.3)	4 (0.8)	7 (0.5)
	Without	969 (99.7)	479 (99.2)	1448 (99.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Nasal Polyps - n (%)	With	19 (2.0)	15 (3.1)	34 (2.3)
	Without	953 (98.0)	468 (96.9)	1421 (97.7)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.2
Subject Disposition
(ITT_M Population)

Status	Upadacitinib(N=972) n (%)	Placebo(N=483) n (%)	Total(N=1455) n (%)
Received study drug in DB period	972 (100.0)	483 (100.0)	1E3 (100.0)
Received first rescue medication in DB period	81 (8.3)	215 (44.5)	296 (20.3)
Received first topical rescue medication in DB period	70 (7.2)	196 (40.6)	266 (18.3)
Plain topical corticosteroid in DB period	69 (7.1)	189 (39.1)	258 (17.7)
High potency topical corticosteroid in DB period	31 (3.2)	122 (25.3)	153 (10.5)
Medium potency topical corticosteroid in DB period	37 (3.8)	84 (17.4)	121 (8.3)
Low potency topical corticosteroid in DB period	18 (1.9)	51 (10.6)	69 (4.7)
Topical calcineurin inhibitor in DB period	6 (0.6)	27 (5.6)	33 (2.3)
Other topical therapy in DB period	2 (0.2)	1 (0.2)	3 (0.2)
Received first systemic rescue medication in DB period	20 (2.1)	56 (11.6)	76 (5.2)
Biologic systemic therapy in DB period	2 (0.2)	7 (1.4)	9 (0.6)
Non-biologic immunomodulating systemic therapy in DB period	17 (1.7)	51 (10.6)	68 (4.7)
Other systemic therapy in DB period	1 (0.1)	2 (0.4)	3 (0.2)
Received first rescue phototherapy in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Completed DB period	927 (95.4)	408 (84.5)	1E3 (91.8)
Ongoing DB Period	6 (0.6)	16 (3.3)	22 (1.5)
Discontinued study in DB period	39 (4.0)	59 (12.2)	98 (6.7)
Primary reason			
Adverse event	11 (1.1)	11 (2.3)	22 (1.5)
Withdrawal of consent	15 (1.5)	27 (5.6)	42 (2.9)
Lost to follow-up	5 (0.5)	1 (0.2)	6 (0.4)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	8 (0.8)	20 (4.1)	28 (1.9)
Completed DB period on study drug	919 (94.5)	408 (84.5)	1E3 (91.2)
Ongoing DB Period on study drug	4 (0.4)	7 (1.4)	11 (0.8)
Discontinued study drug in DB period	49 (5.0)	68 (14.1)	117 (8.0)
Primary reason			
Adverse event	18 (1.9)	13 (2.7)	31 (2.1)
Withdrawal of consent	12 (1.2)	19 (3.9)	31 (2.1)
Lost to follow-up	6 (0.6)	3 (0.6)	9 (0.6)
Lack of efficacy	4 (0.4)	19 (3.9)	23 (1.6)
EASI score - worsening of 25%	0 (0.0)	2 (0.4)	2 (0.1)
Systemic rescue	3 (0.3)	5 (1.0)	8 (0.5)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	6 (0.6)	7 (1.4)	13 (0.9)

N: Number of subjects, n: Number of subjects with non-missing status, DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, COVID: Corona Virus Disease
One patient may receive more than one rescue therapy (topical, systemic, phototherapy).
If a patient receives systemic rescue therapy the primary reason for discontinuation of study drug does not necessarily have to be systemic rescue.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.2
Subject Disposition
(ITT_M Population)

Status	Upadacitinib(N=972) n (%)	Placebo(N=483) n (%)	Total(N=1455) n (%)
Entered BE period	927 (95.4)	408 (84.5)	1E3 (91.8)
Received study drug in BE period	915 (94.1)	406 (84.1)	1E3 (90.8)
Received first rescue medication in BE period	21 (2.2)	3 (0.6)	24 (1.6)
Received first topical rescue medication in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Plain topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
High potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Medium potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Low potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Topical calcineurin inhibitor in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Other topical therapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Received first systemic rescue medication in BE period	24 (2.5)	8 (1.7)	32 (2.2)
Biologic systemic therapy in BE period	4 (0.4)	1 (0.2)	5 (0.3)
Non-biologic immunomodulating systemic therapy in BE period	21 (2.2)	7 (1.4)	28 (1.9)
Other systemic therapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Received first rescue phototherapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Ongoing BE Period	880 (90.5)	397 (82.2)	1E3 (87.8)
Discontinued Study in BE period	47 (4.8)	11 (2.3)	58 (4.0)
Primary reason			
Adverse event	9 (0.9)	5 (1.0)	14 (1.0)
Withdrawal of consent	23 (2.4)	2 (0.4)	25 (1.7)
Lost to follow-up	5 (0.5)	3 (0.6)	8 (0.5)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	10 (1.0)	1 (0.2)	11 (0.8)
Ongoing study drug in BE period	853 (87.8)	393 (81.4)	1E3 (85.6)
Discontinued study drug in BE Period	62 (6.4)	13 (2.7)	75 (5.2)
Primary reason			
Adverse event	18 (1.9)	5 (1.0)	23 (1.6)
Withdrawal of consent	15 (1.5)	1 (0.2)	16 (1.1)
Lost to follow-up	5 (0.5)	2 (0.4)	7 (0.5)
Lack of efficacy	18 (1.9)	3 (0.6)	21 (1.4)
EASI score - worsening of 25%	0 (0.0)	0 (0.0)	0 (0.0)
Systemic rescue	1 (0.1)	0 (0.0)	1 (0.1)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	5 (0.5)	2 (0.4)	7 (0.5)

N: Number of subjects, n: Number of subjects with non-missing status, DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, COVID: Corona Virus Disease
One patient may receive more than one rescue therapy (topical, systemic, phototherapy).
If a patient receives systemic rescue therapy the primary reason for discontinuation of study drug does not necessarily have to be systemic rescue.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Table 1.3
Duration of Study and Treatment and Endpoint Observation time at Week 16
(ITT_M Population)

		Upadacitinib (N=972)	Placebo (N=483)	Total (N=1455)
Study duration in DB period (Week 0 - 16) (Weeks)	n (missing)	972 (0)	483 (0)	1455 (0)
	Mean (SD)	15.96 (1.39)	15.62 (4.78)	15.85 (2.98)
	Median	16.00	16.00	16.00
	Q1, Q3	15.86, 16.14	15.71, 16.14	15.86, 16.14
	Min, Max	1.57, 24.43	1.00, 66.00	1.00, 66.00
Treatment duration in DB period (Week 0 - 16) (Weeks)	n (missing)	972 (0)	483 (0)	1455 (0)
	Mean (SD)	15.65 (2.06)	14.51 (4.24)	15.27 (3.01)
	Median	16.00	16.00	16.00
	Q1, Q3	15.86, 16.14	15.71, 16.14	15.86, 16.14
	Min, Max	0.86, 21.43	0.57, 20.71	0.57, 21.43
Observation time for safety at Week 16 (Weeks)	n (missing)	972 (0)	483 (0)	1455 (0)
	Mean (SD)	16.04 (1.37)	15.26 (2.98)	15.78 (2.08)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.29	15.86, 16.29	16.00, 16.29
	Min, Max	5.14, 21.43	4.86, 20.71	4.86, 21.43
Body Surface Area (BSA): Observation time at Week 16 (Weeks)	n (missing)	972 (0)	482 (1)	1454 (1)
	Mean (SD)	15.70 (2.23)	13.91 (4.83)	15.11 (3.43)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.29	15.71, 16.14	15.86, 16.29
	Min, Max	0.14, 19.29	0.14, 18.57	0.14, 19.29
Eczema Area and Severity Index (EASI): Observation time at Week 16 (Weeks)	n (missing)	972 (0)	482 (1)	1454 (1)
	Mean (SD)	15.70 (2.23)	13.92 (4.82)	15.11 (3.42)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.29	15.71, 16.14	15.86, 16.29
	Min, Max	0.14, 19.29	0.14, 18.57	0.14, 19.29
Patient Global Impression of Severity (PGIS): Observation time at Week 16 (Weeks)	n (missing)	972 (0)	482 (1)	1454 (1)
	Mean (SD)	15.60 (2.50)	13.76 (4.98)	14.99 (3.63)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.29	15.57, 16.14	15.86, 16.29
	Min, Max	0.14, 19.29	0.14, 18.57	0.14, 19.29
Worst Pruritus NRS: Observation time at Week 16 (Weeks)	n (missing)	971 (1)	483 (0)	1454 (1)
	Mean (SD)	15.56 (1.96)	13.71 (4.82)	14.95 (3.32)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.14	15.14, 16.14	15.86, 16.14
	Min, Max	1.14, 17.00	0.14, 17.86	0.14, 17.86

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, NRS: Numeric Rating Scale
Study duration is calculated as (date of first dose of study drug - minimum(date of first dose of study drug in BE period, date of end of study) + 1) divided by 7
Treatment duration is calculated as (date of first dose of study drug - date of last dose of study drug in DB period + 1) divided by 7
Observation time for Safety is calculated as (date of first dose of study drug - minimum(date of first dose of study drug in BE period, date of last dose of study drug in DB period + 30) + 1) divided by 7
Observation time for endpoints is calculated as (date of first dose of study drug - date of last non-missing evaluation in DB period + 1) divided by 7. Evaluations after start of systemic rescue or phototherapy are excluded.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.4
Overview Completion Rates
(ITT_M Population)

Endpoint	Visit	Upadacitinib(N=972) n (%)	Placebo(N=483) n (%)
Worst Pruritus Numeric Rating Scale	Baseline	966 (99.4)	477 (98.8)
	Week 1	964 (99.2)	471 (97.5)
	Week 2	968 (99.6)	470 (97.3)
	Week 3	962 (99.0)	456 (94.4)
	Week 4	957 (98.5)	454 (94.0)
	Week 5	952 (97.9)	438 (90.7)
	Week 6	943 (97.0)	438 (90.7)
	Week 7	944 (97.1)	432 (89.4)
	Week 8	945 (97.2)	428 (88.6)
	Week 9	937 (96.4)	427 (88.4)
	Week 10	931 (95.8)	424 (87.8)
	Week 11	928 (95.5)	423 (87.6)
	Week 12	920 (94.7)	419 (86.7)
	Week 13	911 (93.7)	412 (85.3)
	Week 14	907 (93.3)	407 (84.3)
	Week 15	905 (93.1)	404 (83.6)
	Week 16	853 (87.8)	374 (77.4)
Patient Global Impression of Severity (PGIS)	Baseline	954 (98.1)	476 (98.6)
	Week 1	896 (92.2)	442 (91.5)
	Week 2	933 (96.0)	456 (94.4)
	Week 4	940 (96.7)	459 (95.0)
	Week 12	924 (95.1)	428 (88.6)
	Week 16	921 (94.8)	411 (85.1)

N: Number of subjects, n: Number of subjects with non missing values
All observed data will be used in the analysis.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.5
Overview Missings and Rescue Therapy at Week 16
(ITT_M Population)

		Upadacitinib(N=972)							Placebo(N=483)						
		missings			rescue therapy				missings			rescue therapy			
Endpoint	Visit	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)
EASI	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	43 (4.4)	43 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	22 (4.6)	22 (4.6)	0 (0.0)	7 (1.4)	1 (0.2)	6 (1.2)	0 (0.0)
	Week 2	24 (2.5)	24 (2.5)	0 (0.0)	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)	17 (3.5)	17 (3.5)	0 (0.0)	15 (3.1)	4 (0.8)	11 (2.3)	0 (0.0)
	Week 4	20 (2.1)	20 (2.1)	0 (0.0)	2 (0.2)	1 (0.1)	1 (0.1)	0 (0.0)	21 (4.3)	21 (4.3)	0 (0.0)	24 (5.0)	8 (1.7)	16 (3.3)	0 (0.0)
	Week 8	20 (2.1)	20 (2.1)	0 (0.0)	36 (3.7)	31 (3.2)	5 (0.5)	0 (0.0)	42 (8.7)	42 (8.7)	0 (0.0)	143 (29.6)	114 (23.6)	29 (6.0)	0 (0.0)
	Week 12	42 (4.3)	38 (3.9)	4 (0.4)	48 (4.9)	41 (4.2)	7 (0.7)	0 (0.0)	53 (11.0)	52 (10.8)	1 (0.2)	174 (36.0)	141 (29.2)	33 (6.8)	0 (0.0)
	Week 16	42 (4.3)	38 (3.9)	4 (0.4)	66 (6.8)	50 (5.1)	16 (1.6)	0 (0.0)	66 (13.7)	63 (13.0)	3 (0.6)	181 (37.5)	148 (30.6)	33 (6.8)	0 (0.0)
Pruritus	Baseline	6 (0.6)	6 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.2)	6 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	8 (0.8)	8 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (2.5)	12 (2.5)	0 (0.0)	15 (3.1)	3 (0.6)	12 (2.5)	0 (0.0)
	Week 2	4 (0.4)	4 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (2.7)	13 (2.7)	0 (0.0)	16 (3.3)	4 (0.8)	12 (2.5)	0 (0.0)
	Week 3	10 (1.0)	10 (1.0)	0 (0.0)	2 (0.2)	1 (0.1)	1 (0.1)	0 (0.0)	27 (5.6)	27 (5.6)	0 (0.0)	21 (4.3)	7 (1.4)	14 (2.9)	0 (0.0)
	Week 4	15 (1.5)	15 (1.5)	0 (0.0)	3 (0.3)	2 (0.2)	1 (0.1)	0 (0.0)	29 (6.0)	29 (6.0)	0 (0.0)	33 (6.8)	17 (3.5)	16 (3.3)	0 (0.0)
	Week 5	20 (2.1)	20 (2.1)	0 (0.0)	26 (2.7)	24 (2.5)	2 (0.2)	0 (0.0)	45 (9.3)	45 (9.3)	0 (0.0)	126 (26.1)	100 (20.7)	26 (5.4)	0 (0.0)
	Week 6	29 (3.0)	29 (3.0)	0 (0.0)	27 (2.8)	25 (2.6)	2 (0.2)	0 (0.0)	45 (9.3)	45 (9.3)	0 (0.0)	131 (27.1)	103 (21.3)	28 (5.8)	0 (0.0)
	Week 7	28 (2.9)	28 (2.9)	0 (0.0)	32 (3.3)	29 (3.0)	3 (0.3)	0 (0.0)	51 (10.6)	51 (10.6)	0 (0.0)	139 (28.8)	112 (23.2)	27 (5.6)	0 (0.0)
	Week 8	27 (2.8)	27 (2.8)	0 (0.0)	34 (3.5)	31 (3.2)	3 (0.3)	0 (0.0)	55 (11.4)	55 (11.4)	0 (0.0)	143 (29.6)	114 (23.6)	29 (6.0)	0 (0.0)
	Week 9	35 (3.6)	35 (3.6)	0 (0.0)	43 (4.4)	38 (3.9)	5 (0.5)	0 (0.0)	56 (11.6)	56 (11.6)	0 (0.0)	168 (34.8)	136 (28.2)	32 (6.6)	0 (0.0)
	Week 10	41 (4.2)	41 (4.2)	0 (0.0)	44 (4.5)	38 (3.9)	6 (0.6)	0 (0.0)	59 (12.2)	59 (12.2)	0 (0.0)	166 (34.4)	135 (28.0)	31 (6.4)	0 (0.0)
	Week 11	44 (4.5)	44 (4.5)	0 (0.0)	44 (4.5)	37 (3.8)	7 (0.7)	0 (0.0)	60 (12.4)	60 (12.4)	0 (0.0)	169 (35.0)	139 (28.8)	30 (6.2)	0 (0.0)
	Week 12	52 (5.3)	52 (5.3)	0 (0.0)	50 (5.1)	42 (4.3)	8 (0.8)	0 (0.0)	64 (13.3)	64 (13.3)	0 (0.0)	175 (36.2)	142 (29.4)	33 (6.8)	0 (0.0)
	Week 13	61 (6.3)	61 (6.3)	0 (0.0)	59 (6.1)	48 (4.9)	11 (1.1)	0 (0.0)	71 (14.7)	71 (14.7)	0 (0.0)	175 (36.2)	145 (30.0)	30 (6.2)	0 (0.0)
	Week 14	65 (6.7)	65 (6.7)	0 (0.0)	58 (6.0)	48 (4.9)	10 (1.0)	0 (0.0)	76 (15.7)	76 (15.7)	0 (0.0)	178 (36.9)	148 (30.6)	30 (6.2)	0 (0.0)
	Week 15	67 (6.9)	67 (6.9)	0 (0.0)	58 (6.0)	49 (5.0)	9 (0.9)	0 (0.0)	79 (16.4)	79 (16.4)	0 (0.0)	177 (36.6)	145 (30.0)	32 (6.6)	0 (0.0)
	Week 16	119 (12.2)	119 (12.2)	0 (0.0)	55 (5.7)	45 (4.6)	10 (1.0)	0 (0.0)	109 (22.6)	109 (22.6)	0 (0.0)	163 (33.7)	132 (27.3)	31 (6.4)	0 (0.0)
BSA	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	44 (4.5)	44 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	23 (4.8)	23 (4.8)	0 (0.0)	7 (1.4)	1 (0.2)	6 (1.2)	0 (0.0)
	Week 2	24 (2.5)	24 (2.5)	0 (0.0)	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)	18 (3.7)	18 (3.7)	0 (0.0)	15 (3.1)	4 (0.8)	11 (2.3)	0 (0.0)
	Week 4	21 (2.2)	21 (2.2)	0 (0.0)	2 (0.2)	1 (0.1)	1 (0.1)	0 (0.0)	21 (4.3)	21 (4.3)	0 (0.0)	24 (5.0)	8 (1.7)	16 (3.3)	0 (0.0)
	Week 8	22 (2.3)	22 (2.3)	0 (0.0)	36 (3.7)	31 (3.2)	5 (0.5)	0 (0.0)	42 (8.7)	42 (8.7)	0 (0.0)	143 (29.6)	114 (23.6)	29 (6.0)	0 (0.0)
	Week 12	41 (4.2)	37 (3.8)	4 (0.4)	48 (4.9)	41 (4.2)	7 (0.7)	0 (0.0)	54 (11.2)	53 (11.0)	1 (0.2)	174 (36.0)	141 (29.2)	33 (6.8)	0 (0.0)
	Week 16	42 (4.3)	38 (3.9)	4 (0.4)	66 (6.8)	50 (5.1)	16 (1.6)	0 (0.0)	66 (13.7)	63 (13.0)	3 (0.6)	181 (37.5)	148 (30.6)	33 (6.8)	0 (0.0)
PGIS	Baseline	18 (1.9)	18 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (1.4)	7 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	76 (7.8)	76 (7.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (8.5)	41 (8.5)	0 (0.0)	7 (1.4)	1 (0.2)	6 (1.2)	0 (0.0)
	Week 2	39 (4.0)	39 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	27 (5.6)	27 (5.6)	0 (0.0)	15 (3.1)	4 (0.8)	11 (2.3)	0 (0.0)
	Week 4	32 (3.3)	32 (3.3)	0 (0.0)	1 (0.1)	1 (0.1)	0 (0.0)	0 (0.0)	24 (5.0)	24 (5.0)	0 (0.0)	23 (4.8)	7 (1.4)	16 (3.3)	0 (0.0)
	Week 12	48 (4.9)	44 (4.5)	4 (0.4)	51 (5.2)	42 (4.3)	9 (0.9)	0 (0.0)	55 (11.4)	55 (11.4)	0 (0.0)	175 (36.2)	141 (29.2)	34 (7.0)	0 (0.0)
	Week 16	51 (5.2)	47 (4.8)	4 (0.4)	66 (6.8)	50 (5.1)	16 (1.6)	0 (0.0)	72 (14.9)	69 (14.3)	3 (0.6)	180 (37.3)	147 (30.4)	33 (6.8)	0 (0.0)

N: Number of subjects, EASI: Eczema Area and Severity Index, BSA: Body Surface Area, PGIS: Patient Global Impression of Severity
COVID summarizes the number of subjects with missing data due to COVID-19 infection or logistical restriction, No-COVID summarizes all other subjects with missing data.
topical summarizes the number of rescued subjects of the following categories: plain topical corticosteroids, high/medium/low potency topical corticosteroids, topical calcineurin inhibitor, other topical therapy
systemic summarizes the number of rescued subjects of the following categories: biologic systemic therapy, non-biologic immunomodulating systemic therapy, other systemic therapy
photo summarizes the number of rescued subjects with phototherapy.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.1.1
Descriptive Statistics for Mean Values and Change from Baseline - Eczema Area and Severity Index (EASI)
(ITT_M Population)

	Upadacitinib(N=972)					Placebo(N=483)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	972	0 (0.0)	29.41 (11.90)			482	1 (0.2)	28.56 (11.96)		
Week 1	929	43 (4.4)	17.62 (12.26)	929	-11.89 (9.66)	455	28 (5.8)	25.89 (12.88)	455	-2.66 (7.93)
Week 2	947	25 (2.6)	11.60 (10.97)	947	-17.88 (10.88)	455	28 (5.8)	24.10 (13.22)	455	-4.17 (9.97)
Week 4	951	21 (2.2)	7.27 (9.01)	951	-22.15 (11.29)	446	37 (7.7)	22.79 (15.05)	446	-5.29 (11.92)
Week 8	947	25 (2.6)	5.68 (7.59)	947	-23.86 (11.84)	412	71 (14.7)	18.53 (13.79)	412	-9.07 (11.15)
Week 12	923	49 (5.0)	5.21 (7.61)	923	-24.36 (11.85)	397	86 (17.8)	16.21 (12.95)	397	-11.41 (10.98)
Week 16	914	58 (6.0)	5.31 (8.15)	914	-24.22 (12.27)	384	99 (20.5)	15.46 (12.83)	384	-12.14 (12.19)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.1.2
Descriptive Statistics for Mean Values and Change from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT_M Population)

	Upadacitinib(N=972)					Placebo(N=483)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	966	6 (0.6)	7.26 (1.53)			477	6 (1.2)	7.32 (1.60)		
Week 1	964	8 (0.8)	5.24 (2.01)	959	-2.00 (1.76)	459	24 (5.0)	7.09 (1.73)	454	-0.23 (1.13)
Week 2	968	4 (0.4)	3.98 (2.26)	963	-3.27 (2.19)	458	25 (5.2)	6.81 (1.93)	454	-0.46 (1.48)
Week 3	961	11 (1.1)	3.21 (2.29)	956	-4.05 (2.31)	442	41 (8.5)	6.63 (2.00)	438	-0.63 (1.62)
Week 4	956	16 (1.6)	2.88 (2.33)	951	-4.38 (2.42)	438	45 (9.3)	6.45 (2.11)	434	-0.82 (1.92)
Week 5	950	22 (2.3)	2.66 (2.24)	946	-4.61 (2.41)	412	71 (14.7)	5.87 (2.20)	408	-1.36 (2.04)
Week 6	941	31 (3.2)	2.61 (2.27)	937	-4.67 (2.43)	410	73 (15.1)	5.65 (2.32)	406	-1.59 (2.14)
Week 7	941	31 (3.2)	2.63 (2.33)	938	-4.64 (2.50)	405	78 (16.1)	5.54 (2.39)	401	-1.70 (2.21)
Week 8	942	30 (3.1)	2.58 (2.34)	939	-4.69 (2.51)	399	84 (17.4)	5.54 (2.49)	395	-1.70 (2.24)
Week 9	932	40 (4.1)	2.47 (2.35)	928	-4.78 (2.50)	395	88 (18.2)	5.34 (2.42)	391	-1.91 (2.19)
Week 10	925	47 (4.8)	2.53 (2.38)	921	-4.73 (2.55)	393	90 (18.6)	5.27 (2.51)	389	-1.97 (2.28)
Week 11	921	51 (5.2)	2.55 (2.42)	917	-4.71 (2.58)	393	90 (18.6)	5.27 (2.54)	389	-2.00 (2.33)
Week 12	912	60 (6.2)	2.54 (2.45)	908	-4.72 (2.61)	386	97 (20.1)	5.26 (2.53)	382	-2.01 (2.32)
Week 13	900	72 (7.4)	2.48 (2.45)	898	-4.80 (2.64)	382	101 (20.9)	5.16 (2.54)	377	-2.10 (2.35)
Week 14	897	75 (7.7)	2.52 (2.46)	894	-4.75 (2.66)	377	106 (21.9)	5.20 (2.55)	372	-2.07 (2.35)
Week 15	896	76 (7.8)	2.51 (2.47)	892	-4.77 (2.68)	372	111 (23.0)	5.23 (2.51)	368	-2.06 (2.33)
Week 16	843	129 (13.3)	2.51 (2.46)	840	-4.77 (2.69)	343	140 (29.0)	5.14 (2.53)	339	-2.10 (2.41)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.1.3
Descriptive Statistics for Mean Values and Change from Baseline - Body Surface Area (BSA)
(ITT_M Population)

	Upadacitinib(N=972)					Placebo(N=483)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	972	0 (0.0)	46.75 (22.39)			482	1 (0.2)	45.98 (21.99)		
Week 1	928	44 (4.5)	33.89 (22.61)	928	-13.04 (15.26)	454	29 (6.0)	43.76 (23.27)	454	-2.08 (11.70)
Week 2	947	25 (2.6)	24.51 (21.40)	947	-22.34 (19.28)	454	29 (6.0)	41.82 (23.41)	454	-3.79 (14.25)
Week 4	950	22 (2.3)	16.16 (18.44)	950	-30.60 (20.46)	446	37 (7.7)	39.60 (25.50)	446	-5.53 (17.36)
Week 8	945	27 (2.8)	12.34 (15.66)	945	-34.63 (21.67)	412	71 (14.7)	33.11 (24.09)	412	-11.18 (17.97)
Week 12	924	48 (4.9)	11.07 (15.40)	924	-36.06 (21.81)	396	87 (18.0)	30.45 (23.83)	396	-13.89 (18.93)
Week 16	914	58 (6.0)	10.64 (15.48)	914	-36.30 (22.11)	384	99 (20.5)	29.05 (23.52)	384	-15.09 (20.83)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)

Table 2.1.4

Descriptive Statistics for Mean Values and Change from Baseline - Patient Global Impression of Severity (PGIS)

(ITT_M Population)

	Upadacitinib(N=972)					Placebo(N=483)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	954	18 (1.9)	4.43 (1.09)			476	7 (1.4)	4.51 (1.08)		
Week 1	896	76 (7.8)	2.59 (1.25)	887	-1.84 (1.34)	436	47 (9.7)	4.06 (1.26)	434	-0.44 (1.13)
Week 2	933	39 (4.0)	2.13 (1.23)	916	-2.32 (1.39)	445	38 (7.9)	3.90 (1.31)	443	-0.57 (1.20)
Week 4	940	32 (3.3)	1.71 (1.25)	923	-2.73 (1.49)	443	40 (8.3)	3.80 (1.38)	439	-0.67 (1.35)
Week 12	915	57 (5.9)	1.81 (1.42)	898	-2.64 (1.64)	394	89 (18.4)	3.14 (1.37)	389	-1.30 (1.46)
Week 16	905	67 (6.9)	1.77 (1.42)	889	-2.67 (1.61)	378	105 (21.7)	3.26 (1.46)	373	-1.16 (1.54)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.2.1
Mixed Effects Model with Repeated Measure for Changes from Baseline - Eczema Area and Severity Index (EASI)
(ITT_M Population)

Visit	Upadacitinib(N=972) N*	N**	LSMean (SE)	Placebo(N=483) N*	N**	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedge`s g (95% CI)	p-Value	Interaction p-Value
Week 1			-11.62 (0.29)			-2.93 (0.42)	-8.69 (-9.69, -7.69)				
Week 2			-17.65 (0.31)			-4.26 (0.44)	-13.39 (-14.44, -12.34)				
Week 4			-21.98 (0.32)			-5.50 (0.46)	-16.48 (-17.58, -15.38)				
Week 8			-23.58 (0.30)			-9.26 (0.44)	-14.32 (-15.37, -13.27)				
Week 12			-23.95 (0.29)			-11.57 (0.44)	-12.38 (-13.42, -11.34)				
Week 16			-23.77 (0.31)			-12.32 (0.47)	-11.45 (-12.56, -10.34)				
Overall up to Week 16	970	2	-20.42 (0.23)	474	8	-7.64 (0.34)	-12.79 (-13.60, -11.97)	<.0001	-1.74 (-1.87, -1.61)	<.0001	0.5552

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, study, visit and interaction between treatment and visit.
p-Value for interaction from test for heterogeneity of the differences of LSMeans in the studies using Cochrane`s Q statistic.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.2.2
Mixed Effects Model with Repeated Measure for Changes from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT_M Population)

	Upadacitinib(N=972)			Placebo(N=483)						Interaction
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedge`s g (95% CI)	p-Value	p-Value
Week 1			-2.01 (0.05)			-0.21 (0.07)	-1.79 (-1.96, -1.62)				
Week 2			-3.28 (0.06)			-0.45 (0.09)	-2.82 (-3.04, -2.61)				
Week 3			-4.04 (0.07)			-0.58 (0.09)	-3.46 (-3.68, -3.23)				
Week 4			-4.37 (0.07)			-0.77 (0.10)	-3.60 (-3.84, -3.36)				
Week 5			-4.59 (0.07)			-1.27 (0.10)	-3.32 (-3.56, -3.08)				
Week 6			-4.65 (0.07)			-1.53 (0.11)	-3.12 (-3.37, -2.87)				
Week 7			-4.63 (0.07)			-1.62 (0.11)	-3.01 (-3.26, -2.75)				
Week 8			-4.67 (0.07)			-1.64 (0.11)	-3.03 (-3.29, -2.77)				
Week 9			-4.75 (0.07)			-1.82 (0.11)	-2.93 (-3.19, -2.66)				
Week 10			-4.71 (0.08)			-1.88 (0.11)	-2.83 (-3.09, -2.56)				
Week 11			-4.67 (0.08)			-1.89 (0.12)	-2.79 (-3.06, -2.51)				
Week 12			-4.67 (0.08)			-1.91 (0.12)	-2.76 (-3.03, -2.48)				
Week 13			-4.72 (0.08)			-2.00 (0.12)	-2.72 (-3.00, -2.44)				
Week 14			-4.68 (0.08)			-2.01 (0.12)	-2.68 (-2.96, -2.39)				
Week 15			-4.70 (0.08)			-2.01 (0.12)	-2.69 (-2.97, -2.40)				
Week 16			-4.69 (0.08)			-2.00 (0.12)	-2.69 (-2.97, -2.40)				
Overall up to Week 16	966	5	-4.36 (0.06)	463	20	-1.47 (0.09)	-2.89 (-3.11, -2.67)	<.0001	-1.45 (-1.58, -1.33)	<.0001	0.7134

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, study, visit and interaction between treatment and visit.
p-Value for interaction from test for heterogeneity of the differences of LSMeans in the studies using Cochrane`s Q statistic.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.2.3
Mixed Effects Model with Repeated Measure for Changes from Baseline - Body Surface Area (BSA)
(ITT_M Population)

	Upadacitinib(N=972)			Placebo(N=483)						Interaction
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedge`s g (95% CI)	p-Value	p-Value
Week 1			-12.73 (0.46)			-2.28 (0.66)	-10.45 (-12.03, -8.87)				
Week 2			-22.08 (0.53)			-3.73 (0.76)	-18.35 (-20.16, -16.54)				
Week 4			-30.44 (0.55)			-5.61 (0.80)	-24.82 (-26.74, -22.91)				
Week 8			-34.28 (0.55)			-11.15 (0.82)	-23.12 (-25.05, -21.19)				
Week 12			-35.44 (0.56)			-13.78 (0.84)	-21.66 (-23.63, -19.69)				
Week 16			-35.72 (0.58)			-15.09 (0.87)	-20.62 (-22.67, -18.57)				
Overall up to Week 16	970	2	-28.45 (0.41)	474	8	-8.61 (0.60)	-19.84 (-21.26, -18.41)	<.0001	-1.54 (-1.66, -1.42)	<.0001	0.2280

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, study, visit and interaction between treatment and visit.
p-Value for interaction from test for heterogeneity of the differences of LSMeans in the studies using Cochrane`s Q statistic.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.2.4
Mixed Effects Model with Repeated Measure for Changes from Baseline - Patient Global Impression of Severity (PGIS)
(ITT_M Population)

	Upadacitinib(N=972)			Placebo(N=483)			Difference of LSMeans (95% CI)						Interaction
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)				p-Value	Hedge`s g (95% CI)		p-Value
Week 1			-1.85 (0.04)			-0.43 (0.05)	-1.42 (	-1.55,	-1.29)				
Week 2			-2.33 (0.04)			-0.53 (0.06)	-1.79 (	-1.93,	-1.66)				
Week 4			-2.73 (0.04)			-0.63 (0.06)	-2.10 (	-2.24,	-1.96)				
Week 12			-2.62 (0.05)			-1.24 (0.07)	-1.38 (	-1.54,	-1.22)				
Week 16			-2.65 (0.05)			-1.12 (0.07)	-1.53 (	-1.69,	-1.36)				
Overall up to Week 16	951	21	-2.44 (0.03)	468	14	-0.79 (0.05)	-1.64 (	-1.75,	-1.53)	<.0001	-1.66 (-1.79,	-1.53)	<.0001	0.3726

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, study, visit and interaction between treatment and visit.
p-Value for interaction from test for heterogeneity of the differences of LSMeans in the studies using Cochrane`s Q statistic.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.1
Eczema Area and Severity Index (EASI) 75 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	136 (14.0)	7 (1.4)
	Number of imputations (NRI), n (%)	43 (4.4)	28 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	391 (40.2)	18 (3.7)
	Number of imputations (NRI), n (%)	25 (2.6)	28 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	629 (64.7)	35 (7.2)
	Number of imputations (NRI), n (%)	21 (2.2)	37 (7.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	702 (72.2)	66 (13.7)
	Number of imputations (NRI), n (%)	25 (2.6)	71 (14.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	705 (72.6)	84 (17.5)
	Number of imputations (NRI), n (%)	45 (4.6)	85 (17.6)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	1 (0.2)
Week 16	Number of subjects with Response, n (%)	695 (71.5)	95 (19.6)
	Number of imputations (NRI), n (%)	54 (5.6)	96 (19.9)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	3 (0.6)
	Adjusted Analysis		
	Odds Ratio	10.585	
	95% CI	8.098, 13.835	
	p-value	<.0001	
	Relative Risk	3.649	
	95% CI	3.030, 4.395	
	p-value	<.0001	
	Risk Difference	0.520	
	95% CI	0.475, 0.565	
	p-value	<.0001	
	Interaction p-value	0.3101	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.2
Eczema Area and Severity Index (EASI) 90 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	32 (3.3)	3 (0.6)
	Number of imputations (NRI), n (%)	43 (4.4)	28 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	172 (17.7)	3 (0.6)
	Number of imputations (NRI), n (%)	25 (2.6)	28 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	366 (37.7)	12 (2.5)
	Number of imputations (NRI), n (%)	21 (2.2)	37 (7.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	481 (49.5)	21 (4.3)
	Number of imputations (NRI), n (%)	25 (2.6)	71 (14.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	505 (51.9)	29 (6.1)
	Number of imputations (NRI), n (%)	45 (4.6)	85 (17.6)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	1 (0.2)
Week 16	Number of subjects with Response, n (%)	539 (55.4)	41 (8.6)
	Number of imputations (NRI), n (%)	54 (5.6)	96 (19.9)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	3 (0.6)
	Adjusted Analysis		
	Odds Ratio	13.656	
	95% CI	9.655, 19.315	
	p-value	<.0001	
	Relative Risk	6.478	
	95% CI	4.806, 8.731	
	p-value	<.0001	
	Risk Difference	0.465	
	95% CI	0.425, 0.505	
	p-value	<.0001	
	Interaction p-value	0.5901	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.3
Eczema Area and Severity Index (EASI) 100 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	43 (4.4)	28 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	17 (1.7)	0 (0.0)
	Number of imputations (NRI), n (%)	25 (2.6)	28 (5.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	72 (7.4)	3 (0.6)
	Number of imputations (NRI), n (%)	21 (2.2)	37 (7.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	145 (14.9)	6 (1.2)
	Number of imputations (NRI), n (%)	25 (2.6)	71 (14.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	183 (18.8)	5 (1.0)
	Number of imputations (NRI), n (%)	45 (4.6)	85 (17.6)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	1 (0.2)
Week 16	Number of subjects with Response, n (%)	190 (19.6)	7 (1.5)
	Number of imputations (NRI), n (%)	54 (5.6)	96 (19.9)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	3 (0.6)
	Adjusted Analysis		
	Odds Ratio	16.676	
	95% CI	7.771, 35.785	
	p-value	<.0001	
	Relative Risk	13.456	
	95% CI	6.381, 28.377	
	p-value	<.0001	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.4201	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	139 (14.3)	3 (0.6)
	Number of imputations (NRI), n (%)	8 (0.8)	24 (5.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	359 (36.9)	11 (2.3)
	Number of imputations (NRI), n (%)	4 (0.4)	25 (5.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 3	Number of subjects with Response, n (%)	492 (50.6)	20 (4.1)
	Number of imputations (NRI), n (%)	11 (1.1)	41 (8.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	558 (57.4)	22 (4.6)
	Number of imputations (NRI), n (%)	16 (1.6)	45 (9.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 5	Number of subjects with Response, n (%)	586 (60.3)	51 (10.6)
	Number of imputations (NRI), n (%)	22 (2.3)	71 (14.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 6	Number of subjects with Response, n (%)	592 (60.9)	56 (11.6)
	Number of imputations (NRI), n (%)	31 (3.2)	73 (15.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 7	Number of subjects with Response, n (%)	587 (60.4)	57 (11.8)
	Number of imputations (NRI), n (%)	31 (3.2)	78 (16.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	620 (63.8)	66 (13.7)
	Number of imputations (NRI), n (%)	30 (3.1)	84 (17.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 9	Number of subjects with Response, n (%)	607 (62.4)	70 (14.5)
	Number of imputations (NRI), n (%)	40 (4.1)	88 (18.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 10	Number of subjects with Response, n (%)	596 (61.3)	74 (15.3)
	Number of imputations (NRI), n (%)	47 (4.8)	90 (18.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 11	Number of subjects with Response, n (%)	589 (60.6)	81 (16.8)
	Number of imputations (NRI), n (%)	51 (5.2)	90 (18.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	587 (60.4)	79 (16.4)
	Number of imputations (NRI), n (%)	60 (6.2)	97 (20.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 13	Number of subjects with Response, n (%)	587 (60.4)	84 (17.4)
	Number of imputations (NRI), n (%)	72 (7.4)	101 (20.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 14	Number of subjects with Response, n (%)	587 (60.4)	78 (16.1)
	Number of imputations (NRI), n (%)	75 (7.7)	106 (21.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 15	Number of subjects with Response, n (%)	589 (60.6)	78 (16.1)
	Number of imputations (NRI), n (%)	76 (7.8)	111 (23.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	537 (55.2)	79 (16.4)
	Number of imputations (NRI), n (%)	129 (13.3)	140 (29.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	6.402	
	95% CI	4.870, 8.417	
	p-value	<.0001	
	Relative Risk	3.367	
	95% CI	2.731, 4.150	
	p-value	<.0001	
	Risk Difference	0.387	
	95% CI	0.342, 0.432	
	p-value	<.0001	
	Interaction p-value	0.2520	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	1 (0.1)	0 (0.0)
	Number of imputations (NRI), n (%)	8 (0.8)	24 (5.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	19 (2.0)	2 (0.4)
	Number of imputations (NRI), n (%)	4 (0.4)	25 (5.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 3	Number of subjects with Response, n (%)	56 (5.8)	1 (0.2)
	Number of imputations (NRI), n (%)	11 (1.1)	41 (8.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	80 (8.2)	2 (0.4)
	Number of imputations (NRI), n (%)	16 (1.6)	45 (9.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 5	Number of subjects with Response, n (%)	95 (9.8)	1 (0.2)
	Number of imputations (NRI), n (%)	22 (2.3)	71 (14.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 6	Number of subjects with Response, n (%)	121 (12.4)	2 (0.4)
	Number of imputations (NRI), n (%)	31 (3.2)	73 (15.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 7	Number of subjects with Response, n (%)	133 (13.7)	3 (0.6)
	Number of imputations (NRI), n (%)	31 (3.2)	78 (16.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	145 (14.9)	4 (0.8)
	Number of imputations (NRI), n (%)	30 (3.1)	84 (17.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 9	Number of subjects with Response, n (%)	149 (15.3)	4 (0.8)
	Number of imputations (NRI), n (%)	40 (4.1)	88 (18.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 10	Number of subjects with Response, n (%)	152 (15.6)	10 (2.1)
	Number of imputations (NRI), n (%)	47 (4.8)	90 (18.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 11	Number of subjects with Response, n (%)	153 (15.7)	3 (0.6)
	Number of imputations (NRI), n (%)	51 (5.2)	90 (18.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	174 (17.9)	8 (1.7)
	Number of imputations (NRI), n (%)	60 (6.2)	97 (20.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 13	Number of subjects with Response, n (%)	183 (18.8)	8 (1.7)
	Number of imputations (NRI), n (%)	72 (7.4)	101 (20.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 14	Number of subjects with Response, n (%)	185 (19.0)	4 (0.8)
	Number of imputations (NRI), n (%)	75 (7.7)	106 (21.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 15	Number of subjects with Response, n (%)	183 (18.8)	10 (2.1)
	Number of imputations (NRI), n (%)	76 (7.8)	111 (23.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	185 (19.0)	9 (1.9)
	Number of imputations (NRI), n (%)	129 (13.3)	140 (29.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	12.438	
	95% CI	6.309, 24.524	
	p-value	<.0001	
	Relative Risk	10.243	
	95% CI	5.294, 19.816	
	p-value	<.0001	
	Risk Difference	0.172	
	95% CI	0.144, 0.199	
	p-value	<.0001	
	Interaction p-value	0.2181	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.6
Body Surface Area (BSA) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	44 (4.5)	29 (6.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	16 (1.6)	0 (0.0)
	Number of imputations (NRI), n (%)	25 (2.6)	29 (6.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	74 (7.6)	3 (0.6)
	Number of imputations (NRI), n (%)	22 (2.3)	37 (7.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	146 (15.0)	6 (1.2)
	Number of imputations (NRI), n (%)	27 (2.8)	71 (14.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	181 (18.6)	6 (1.2)
	Number of imputations (NRI), n (%)	44 (4.5)	86 (17.8)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	1 (0.2)
Week 16	Number of subjects with Response, n (%)	193 (19.9)	8 (1.7)
	Number of imputations (NRI), n (%)	54 (5.6)	96 (19.9)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	3 (0.6)
	Adjusted Analysis		
	Odds Ratio	14.860	
	95% CI	7.254, 30.438	
	p-value	<.0001	
	Relative Risk	11.955	
	95% CI	5.946, 24.037	
	p-value	<.0001	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.2610	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.7
Patient Global Impression of Severity (PGIS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	16 (1.6)	0 (0.0)
	Number of imputations (NRI), n (%)	76 (7.8)	47 (9.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	42 (4.3)	2 (0.4)
	Number of imputations (NRI), n (%)	39 (4.0)	38 (7.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	113 (11.6)	2 (0.4)
	Number of imputations (NRI), n (%)	32 (3.3)	40 (8.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	156 (16.0)	8 (1.7)
	Number of imputations (NRI), n (%)	53 (5.5)	89 (18.4)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	171 (17.6)	10 (2.1)
	Number of imputations (NRI), n (%)	63 (6.5)	102 (21.1)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.4)	3 (0.6)
	Adjusted Analysis		
	Odds Ratio	10.127	
	95% CI	5.296, 19.366	
	p-value	<.0001	
	Relative Risk	8.469	
	95% CI	4.520, 15.871	
	p-value	<.0001	
	Risk Difference	0.153	
	95% CI	0.125, 0.180	
	p-value	<.0001	
	Interaction p-value	0.3047	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio/Relative Risk/Risk Difference, CI and p-value based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and logit-link/log-link/identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.1
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 75 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	140 (14.4)	7 (1.5)
	Number of imputations (NRI), n (%)	0 (0.0)	6 (1.2)
	Number of imputations (MI), n (%)	43 (4.4)	22 (4.6)
Week 2	Number of subjects with Response, n (%)	397 (40.8)	19 (3.8)
	Number of imputations (NRI), n (%)	1 (0.1)	11 (2.3)
	Number of imputations (MI), n (%)	24 (2.5)	17 (3.5)
Week 4	Number of subjects with Response, n (%)	634 (65.2)	35 (7.3)
	Number of imputations (NRI), n (%)	1 (0.1)	16 (3.3)
	Number of imputations (MI), n (%)	20 (2.1)	21 (4.3)
Week 8	Number of subjects with Response, n (%)	708 (72.9)	69 (14.3)
	Number of imputations (NRI), n (%)	5 (0.5)	29 (6.0)
	Number of imputations (MI), n (%)	20 (2.1)	42 (8.7)
Week 12	Number of subjects with Response, n (%)	719 (74.0)	89 (18.5)
	Number of imputations (NRI), n (%)	7 (0.7)	33 (6.8)
	Number of imputations (MI), n (%)	42 (4.3)	53 (11.0)
Week 16	Number of subjects with Response, n (%)	708 (72.8)	101 (20.9)
	Number of imputations (NRI), n (%)	16 (1.6)	33 (6.8)
	Number of imputations (MI), n (%)	42 (4.3)	66 (13.7)
	Adjusted Analysis		
	Odds Ratio	10.430	
	95% CI	7.959, 13.668	
	p-value	<.0001	
	Relative Risk	3.486	
	95% CI	2.903, 4.187	
	p-value	<.0001	
	Risk Difference	0.520	
	95% CI	0.473, 0.566	
	p-value	<.0001	
	Interaction p-value	0.3532	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.2
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 90 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	33 (3.4)	3 (0.6)
	Number of imputations (NRI), n (%)	0 (0.0)	6 (1.2)
	Number of imputations (MI), n (%)	43 (4.4)	22 (4.6)
Week 2	Number of subjects with Response, n (%)	173 (17.8)	3 (0.6)
	Number of imputations (NRI), n (%)	1 (0.1)	11 (2.3)
	Number of imputations (MI), n (%)	24 (2.5)	17 (3.5)
Week 4	Number of subjects with Response, n (%)	367 (37.8)	12 (2.5)
	Number of imputations (NRI), n (%)	1 (0.1)	16 (3.3)
	Number of imputations (MI), n (%)	20 (2.1)	21 (4.3)
Week 8	Number of subjects with Response, n (%)	482 (49.6)	22 (4.5)
	Number of imputations (NRI), n (%)	5 (0.5)	29 (6.0)
	Number of imputations (MI), n (%)	20 (2.1)	42 (8.7)
Week 12	Number of subjects with Response, n (%)	510 (52.4)	30 (6.3)
	Number of imputations (NRI), n (%)	7 (0.7)	33 (6.8)
	Number of imputations (MI), n (%)	42 (4.3)	53 (11.0)
Week 16	Number of subjects with Response, n (%)	544 (55.9)	43 (8.9)
	Number of imputations (NRI), n (%)	16 (1.6)	33 (6.8)
	Number of imputations (MI), n (%)	42 (4.3)	66 (13.7)
	Adjusted Analysis		
	Odds Ratio	13.286	
	95% CI	9.406, 18.766	
	p-value	<.0001	
	Relative Risk	6.260	
	95% CI	4.658, 8.412	
	p-value	<.0001	
	Risk Difference	0.466	
	95% CI	0.425, 0.507	
	p-value	<.0001	
	Interaction p-value	0.6562	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.3
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 100 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	6 (1.2)
	Number of imputations (MI), n (%)	43 (4.4)	22 (4.6)
Week 2	Number of subjects with Response, n (%)	17 (1.8)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (0.1)	11 (2.3)
	Number of imputations (MI), n (%)	24 (2.5)	17 (3.5)
Week 4	Number of subjects with Response, n (%)	71 (7.3)	3 (0.6)
	Number of imputations (NRI), n (%)	1 (0.1)	16 (3.3)
	Number of imputations (MI), n (%)	20 (2.1)	21 (4.3)
Week 8	Number of subjects with Response, n (%)	144 (14.8)	6 (1.2)
	Number of imputations (NRI), n (%)	5 (0.5)	29 (6.0)
	Number of imputations (MI), n (%)	20 (2.1)	42 (8.7)
Week 12	Number of subjects with Response, n (%)	183 (18.9)	5 (1.0)
	Number of imputations (NRI), n (%)	7 (0.7)	33 (6.8)
	Number of imputations (MI), n (%)	42 (4.3)	53 (11.0)
Week 16	Number of subjects with Response, n (%)	190 (19.6)	7 (1.5)
	Number of imputations (NRI), n (%)	16 (1.6)	33 (6.8)
	Number of imputations (MI), n (%)	42 (4.3)	66 (13.7)
	Adjusted Analysis		
	Odds Ratio	16.615	
	95% CI	7.742, 35.657	
	p-value	<.0001	
	Relative Risk	13.406	
	95% CI	6.357, 28.271	
	p-value	<.0001	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.4311	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	140 (14.4)	3 (0.6)
	Number of imputations (NRI), n (%)	0 (0.0)	12 (2.5)
	Number of imputations (MI), n (%)	8 (0.8)	12 (2.5)
Week 2	Number of subjects with Response, n (%)	360 (37.0)	11 (2.3)
	Number of imputations (NRI), n (%)	0 (0.0)	12 (2.5)
	Number of imputations (MI), n (%)	4 (0.4)	13 (2.7)
Week 3	Number of subjects with Response, n (%)	495 (50.9)	21 (4.3)
	Number of imputations (NRI), n (%)	1 (0.1)	14 (2.9)
	Number of imputations (MI), n (%)	10 (1.0)	27 (5.6)
Week 4	Number of subjects with Response, n (%)	562 (57.8)	24 (4.9)
	Number of imputations (NRI), n (%)	1 (0.1)	16 (3.3)
	Number of imputations (MI), n (%)	15 (1.5)	29 (6.0)
Week 5	Number of subjects with Response, n (%)	594 (61.1)	55 (11.4)
	Number of imputations (NRI), n (%)	2 (0.2)	26 (5.4)
	Number of imputations (MI), n (%)	20 (2.1)	45 (9.3)
Week 6	Number of subjects with Response, n (%)	602 (61.9)	63 (13.1)
	Number of imputations (NRI), n (%)	2 (0.2)	28 (5.8)
	Number of imputations (MI), n (%)	29 (3.0)	45 (9.3)
Week 7	Number of subjects with Response, n (%)	598 (61.5)	66 (13.6)
	Number of imputations (NRI), n (%)	3 (0.3)	27 (5.6)
	Number of imputations (MI), n (%)	28 (2.9)	51 (10.6)
Week 8	Number of subjects with Response, n (%)	632 (65.0)	75 (15.5)
	Number of imputations (NRI), n (%)	3 (0.3)	29 (6.0)
	Number of imputations (MI), n (%)	27 (2.8)	55 (11.4)
Week 9	Number of subjects with Response, n (%)	622 (64.0)	80 (16.5)
	Number of imputations (NRI), n (%)	5 (0.5)	32 (6.6)
	Number of imputations (MI), n (%)	35 (3.6)	56 (11.6)
Week 10	Number of subjects with Response, n (%)	612 (62.9)	84 (17.4)
	Number of imputations (NRI), n (%)	6 (0.6)	31 (6.4)
	Number of imputations (MI), n (%)	41 (4.2)	59 (12.2)
Week 11	Number of subjects with Response, n (%)	608 (62.6)	91 (18.8)
	Number of imputations (NRI), n (%)	7 (0.7)	30 (6.2)
	Number of imputations (MI), n (%)	44 (4.5)	60 (12.4)
Week 12	Number of subjects with Response, n (%)	611 (62.8)	91 (18.8)
	Number of imputations (NRI), n (%)	8 (0.8)	33 (6.8)
	Number of imputations (MI), n (%)	52 (5.3)	64 (13.3)
Week 13	Number of subjects with Response, n (%)	611 (62.9)	98 (20.4)
	Number of imputations (NRI), n (%)	11 (1.1)	30 (6.2)
	Number of imputations (MI), n (%)	61 (6.3)	71 (14.7)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 14	Number of subjects with Response, n (%)	616 (63.4)	95 (19.7)
	Number of imputations (NRI), n (%)	10 (1.0)	30 (6.2)
	Number of imputations (MI), n (%)	65 (6.7)	76 (15.7)
Week 15	Number of subjects with Response, n (%)	620 (63.8)	96 (19.8)
	Number of imputations (NRI), n (%)	9 (0.9)	32 (6.6)
	Number of imputations (MI), n (%)	67 (6.9)	79 (16.4)
Week 16	Number of subjects with Response, n (%)	604 (62.2)	101 (21.0)
	Number of imputations (NRI), n (%)	10 (1.0)	31 (6.4)
	Number of imputations (MI), n (%)	119 (12.2)	109 (22.6)
	Adjusted Analysis		
	Odds Ratio	6.274	
	95% CI	4.788, 8.220	
	p-value	<.0001	
	Relative Risk	2.955	
	95% CI	2.442, 3.576	
	p-value	<.0001	
	Risk Difference	0.410	
	95% CI	0.361, 0.459	
	p-value	<.0001	
	Interaction p-value	0.5327	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	1 (0.1)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	12 (2.5)
	Number of imputations (MI), n (%)	8 (0.8)	12 (2.5)
Week 2	Number of subjects with Response, n (%)	19 (2.0)	2 (0.4)
	Number of imputations (NRI), n (%)	0 (0.0)	12 (2.5)
	Number of imputations (MI), n (%)	4 (0.4)	13 (2.7)
Week 3	Number of subjects with Response, n (%)	56 (5.8)	1 (0.2)
	Number of imputations (NRI), n (%)	1 (0.1)	14 (2.9)
	Number of imputations (MI), n (%)	10 (1.0)	27 (5.6)
Week 4	Number of subjects with Response, n (%)	80 (8.2)	2 (0.4)
	Number of imputations (NRI), n (%)	1 (0.1)	16 (3.3)
	Number of imputations (MI), n (%)	15 (1.5)	29 (6.0)
Week 5	Number of subjects with Response, n (%)	95 (9.8)	1 (0.2)
	Number of imputations (NRI), n (%)	2 (0.2)	26 (5.4)
	Number of imputations (MI), n (%)	20 (2.1)	45 (9.3)
Week 6	Number of subjects with Response, n (%)	121 (12.4)	2 (0.4)
	Number of imputations (NRI), n (%)	2 (0.2)	28 (5.8)
	Number of imputations (MI), n (%)	29 (3.0)	45 (9.3)
Week 7	Number of subjects with Response, n (%)	133 (13.7)	3 (0.6)
	Number of imputations (NRI), n (%)	3 (0.3)	27 (5.6)
	Number of imputations (MI), n (%)	28 (2.9)	51 (10.6)
Week 8	Number of subjects with Response, n (%)	145 (14.9)	4 (0.8)
	Number of imputations (NRI), n (%)	3 (0.3)	29 (6.0)
	Number of imputations (MI), n (%)	27 (2.8)	55 (11.4)
Week 9	Number of subjects with Response, n (%)	149 (15.3)	4 (0.8)
	Number of imputations (NRI), n (%)	5 (0.5)	32 (6.6)
	Number of imputations (MI), n (%)	35 (3.6)	56 (11.6)
Week 10	Number of subjects with Response, n (%)	151 (15.5)	10 (2.1)
	Number of imputations (NRI), n (%)	6 (0.6)	31 (6.4)
	Number of imputations (MI), n (%)	41 (4.2)	59 (12.2)
Week 11	Number of subjects with Response, n (%)	153 (15.7)	3 (0.6)
	Number of imputations (NRI), n (%)	7 (0.7)	30 (6.2)
	Number of imputations (MI), n (%)	44 (4.5)	60 (12.4)
Week 12	Number of subjects with Response, n (%)	174 (17.9)	8 (1.7)
	Number of imputations (NRI), n (%)	8 (0.8)	33 (6.8)
	Number of imputations (MI), n (%)	52 (5.3)	64 (13.3)
Week 13	Number of subjects with Response, n (%)	182 (18.7)	8 (1.7)
	Number of imputations (NRI), n (%)	11 (1.1)	30 (6.2)
	Number of imputations (MI), n (%)	61 (6.3)	71 (14.7)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 14	Number of subjects with Response, n (%)	184 (18.9)	4 (0.8)
	Number of imputations (NRI), n (%)	10 (1.0)	30 (6.2)
	Number of imputations (MI), n (%)	65 (6.7)	76 (15.7)
Week 15	Number of subjects with Response, n (%)	183 (18.8)	10 (2.1)
	Number of imputations (NRI), n (%)	9 (0.9)	32 (6.6)
	Number of imputations (MI), n (%)	67 (6.9)	79 (16.4)
Week 16	Number of subjects with Response, n (%)	185 (19.0)	9 (1.9)
	Number of imputations (NRI), n (%)	10 (1.0)	31 (6.4)
	Number of imputations (MI), n (%)	119 (12.2)	109 (22.6)
	Adjusted Analysis		
	Odds Ratio	12.438	
	95% CI	6.309, 24.524	
	p-value	<.0001	
	Relative Risk	10.243	
	95% CI	5.294, 19.816	
	p-value	<.0001	
	Risk Difference	0.172	
	95% CI	0.144, 0.199	
	p-value	<.0001	
	Interaction p-value	0.2181	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.6
Sensitivity Analysis of Body Surface Area (BSA) = 0 (NRI/MI)
(ITT_M Population)

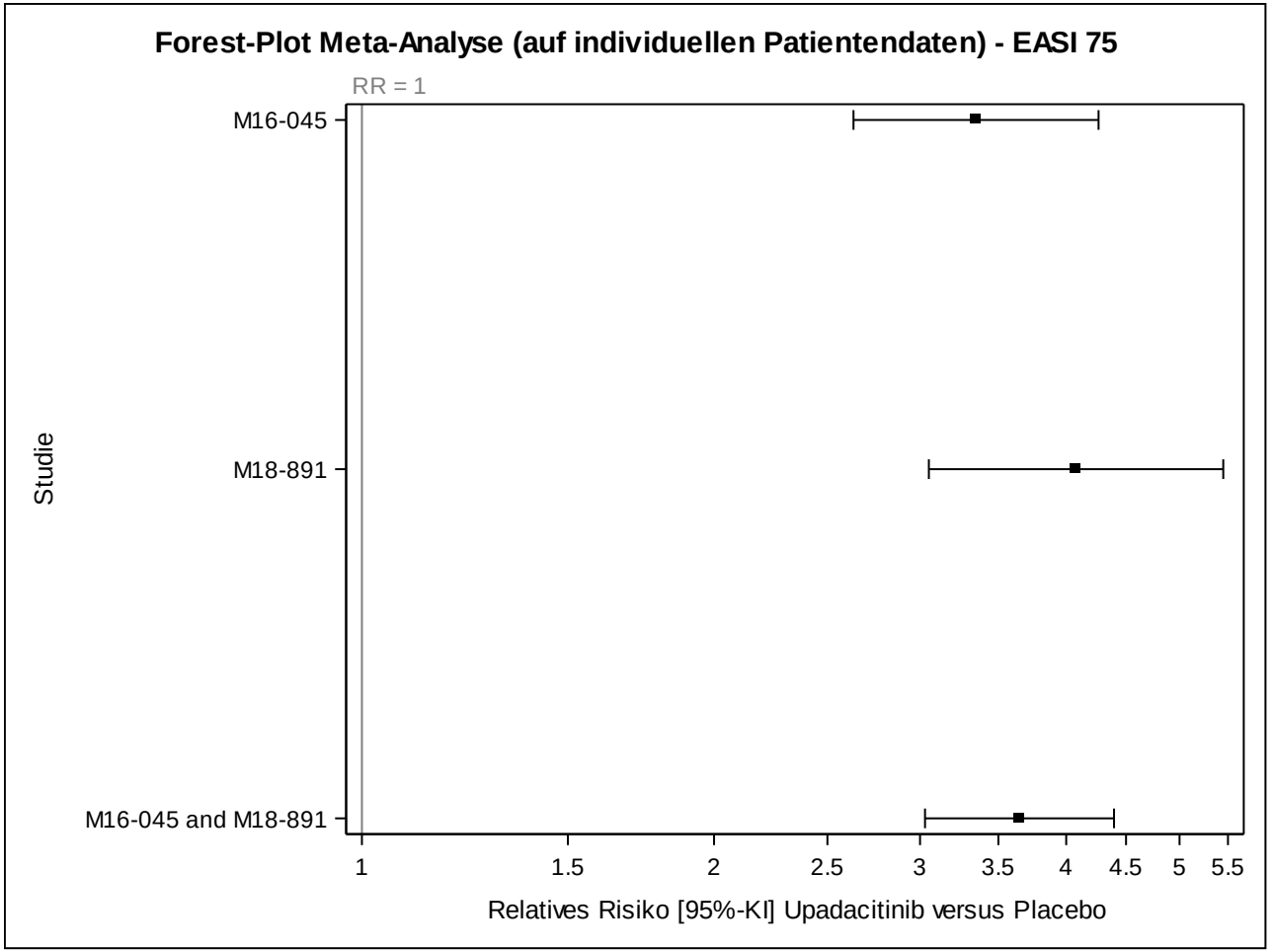
Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	6 (1.2)
	Number of imputations (MI), n (%)	44 (4.5)	23 (4.8)
Week 2	Number of subjects with Response, n (%)	16 (1.6)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (0.1)	11 (2.3)
	Number of imputations (MI), n (%)	24 (2.5)	18 (3.7)
Week 4	Number of subjects with Response, n (%)	73 (7.5)	3 (0.6)
	Number of imputations (NRI), n (%)	1 (0.1)	16 (3.3)
	Number of imputations (MI), n (%)	21 (2.2)	21 (4.3)
Week 8	Number of subjects with Response, n (%)	145 (14.9)	6 (1.2)
	Number of imputations (NRI), n (%)	5 (0.5)	29 (6.0)
	Number of imputations (MI), n (%)	22 (2.3)	42 (8.7)
Week 12	Number of subjects with Response, n (%)	181 (18.6)	6 (1.2)
	Number of imputations (NRI), n (%)	7 (0.7)	33 (6.8)
	Number of imputations (MI), n (%)	41 (4.2)	54 (11.2)
Week 16	Number of subjects with Response, n (%)	193 (19.9)	8 (1.7)
	Number of imputations (NRI), n (%)	16 (1.6)	33 (6.8)
	Number of imputations (MI), n (%)	42 (4.3)	66 (13.7)
	Adjusted Analysis		
	Odds Ratio	14.875	
	95% CI	7.262, 30.470	
	p-value	<.0001	
	Relative Risk	11.965	
	95% CI	5.951, 24.058	
	p-value	<.0001	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.2611	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

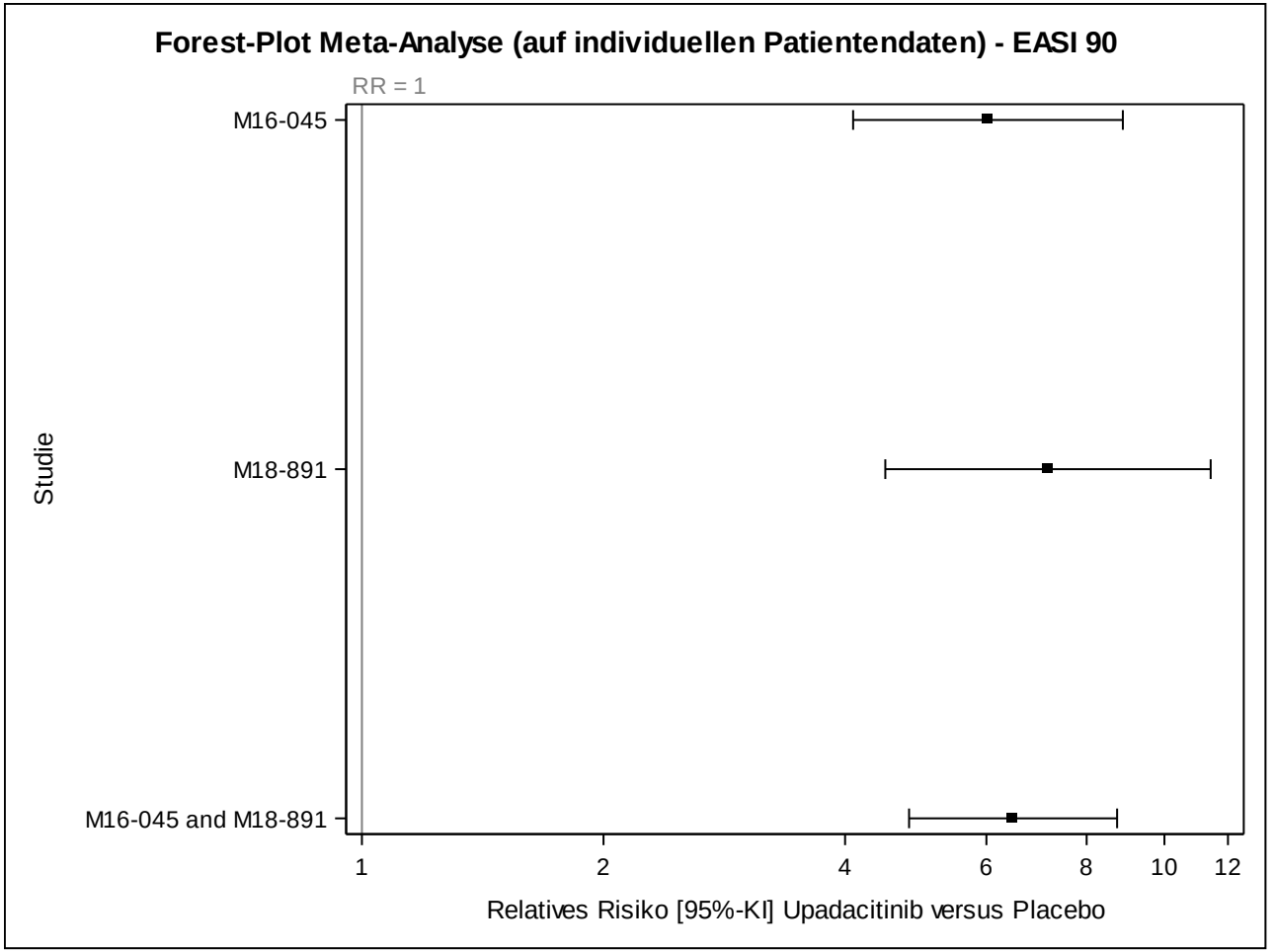
Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.7
Sensitivity Analysis of Patient Global Impression of Severity (PGIS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 1	Number of subjects with Response, n (%)	18 (1.8)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	6 (1.2)
	Number of imputations (MI), n (%)	76 (7.8)	41 (8.5)
Week 2	Number of subjects with Response, n (%)	46 (4.7)	2 (0.4)
	Number of imputations (NRI), n (%)	0 (0.0)	11 (2.3)
	Number of imputations (MI), n (%)	39 (4.0)	27 (5.6)
Week 4	Number of subjects with Response, n (%)	117 (12.1)	2 (0.4)
	Number of imputations (NRI), n (%)	0 (0.0)	16 (3.3)
	Number of imputations (MI), n (%)	32 (3.3)	24 (5.0)
Week 12	Number of subjects with Response, n (%)	161 (16.6)	10 (2.0)
	Number of imputations (NRI), n (%)	9 (0.9)	34 (7.0)
	Number of imputations (MI), n (%)	48 (4.9)	55 (11.4)
Week 16	Number of subjects with Response, n (%)	179 (18.4)	12 (2.4)
	Number of imputations (NRI), n (%)	16 (1.6)	33 (6.8)
	Number of imputations (MI), n (%)	51 (5.2)	72 (14.9)
	Adjusted Analysis		
	Odds Ratio	9.332	
	95% CI	4.906, 17.751	
	p-value	<.0001	
	Relative Risk	7.746	
	95% CI	4.163, 14.415	
	p-value	<.0001	
	Risk Difference	0.158	
	95% CI	0.129, 0.187	
	p-value	<.0001	
	Interaction p-value	0.2836	

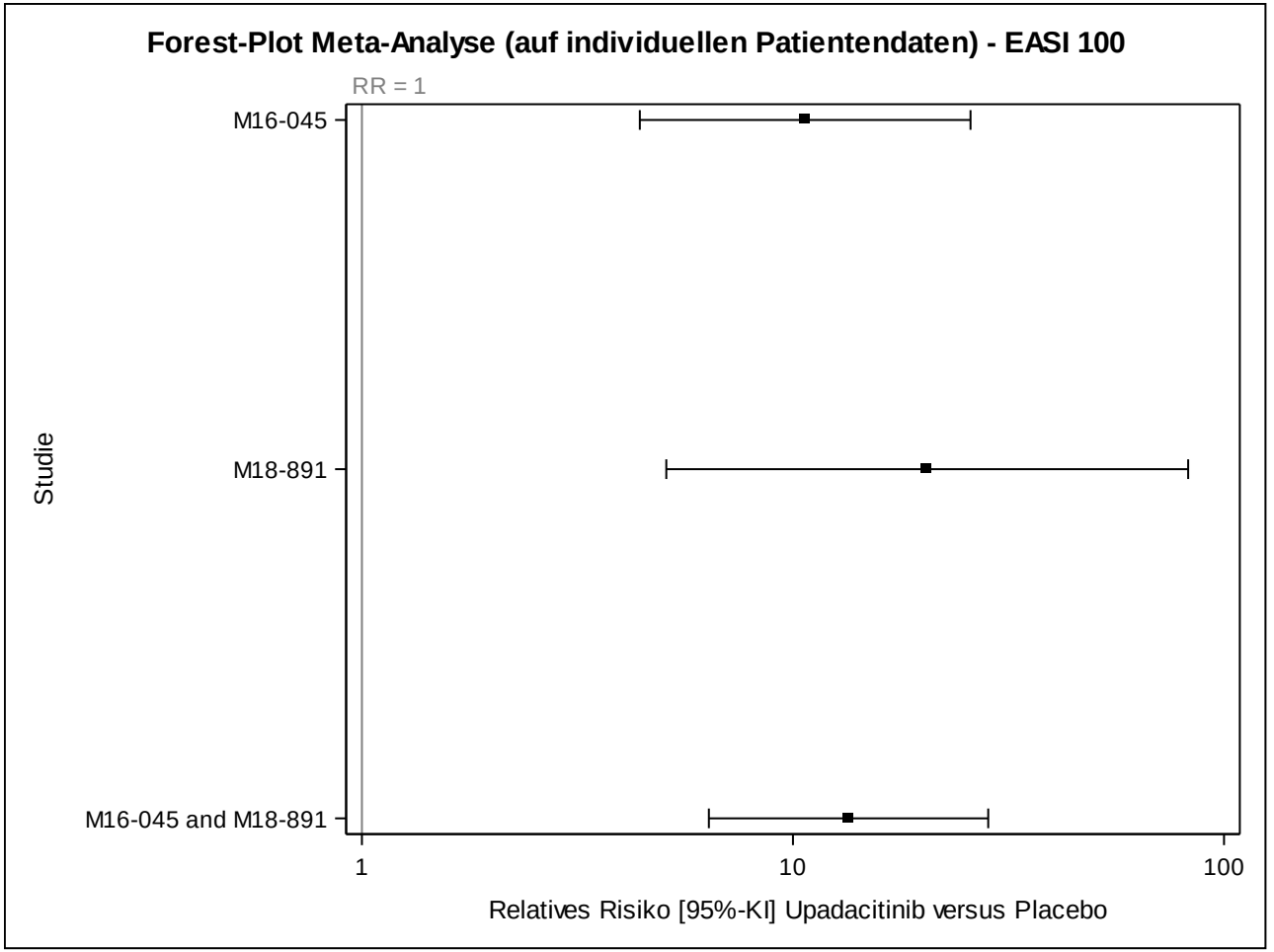
N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
p-Value for interaction from a generalized linear model with treatment, vIGA-AD categories, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.



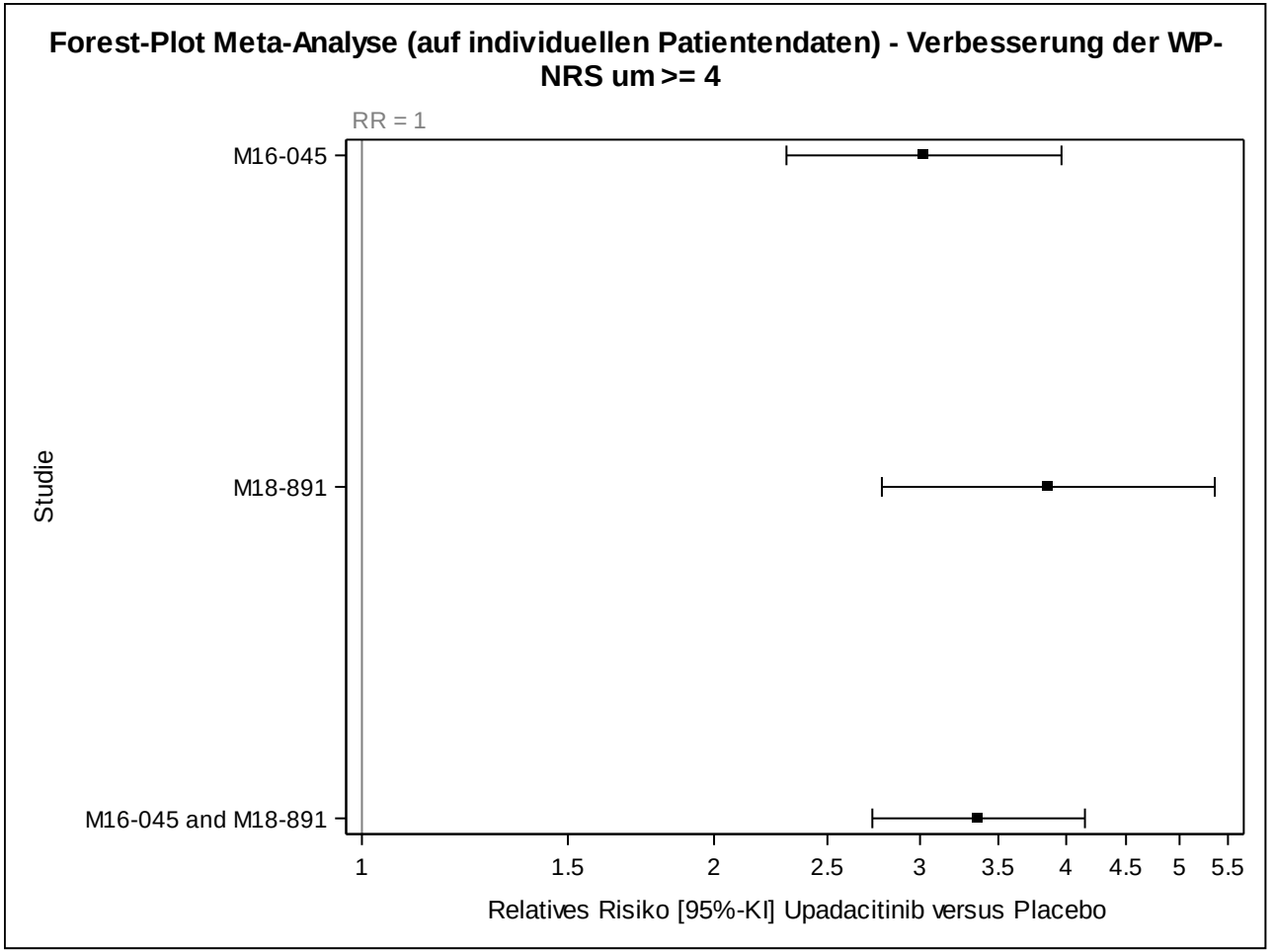
modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.



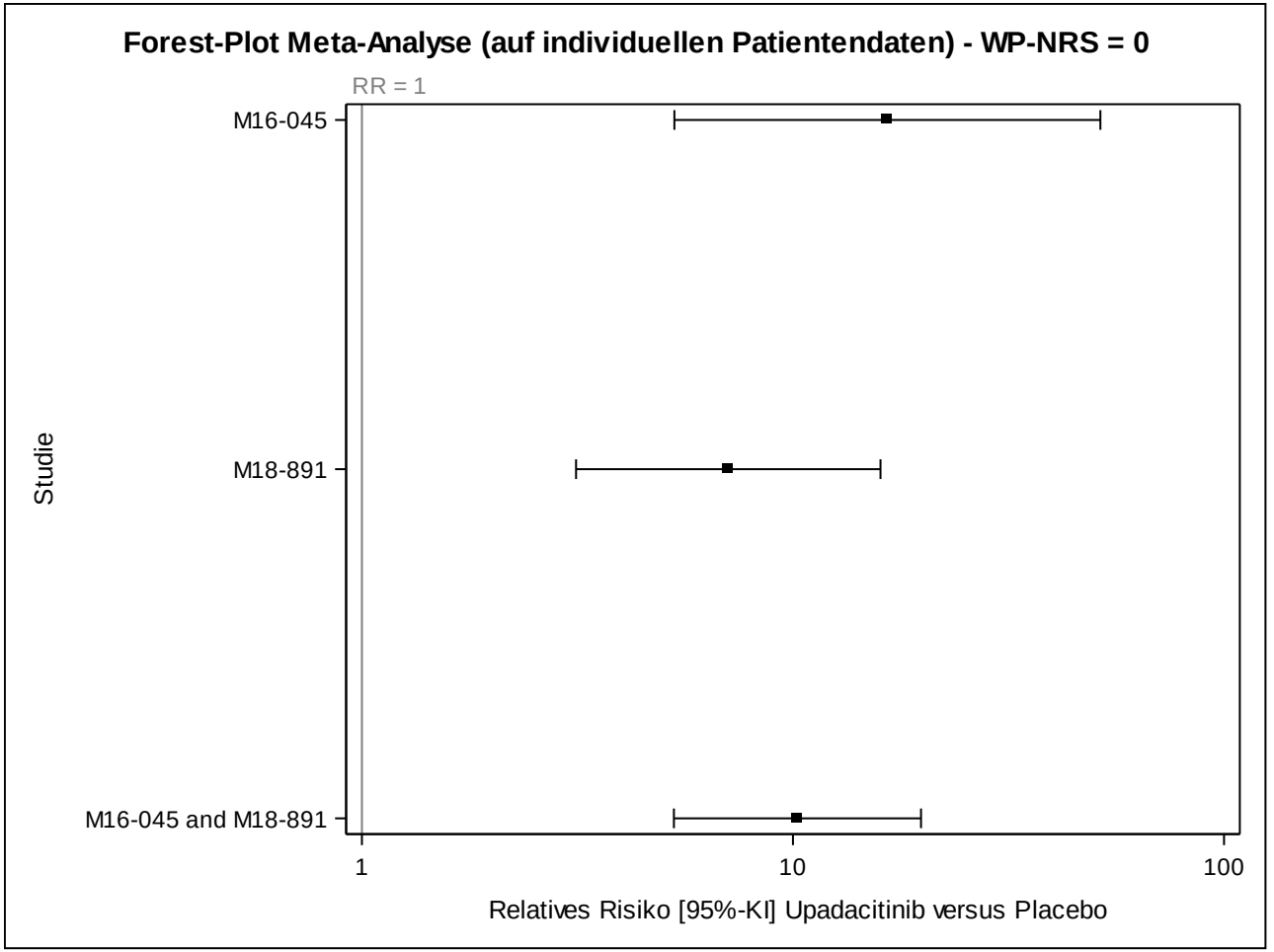
modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.



modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

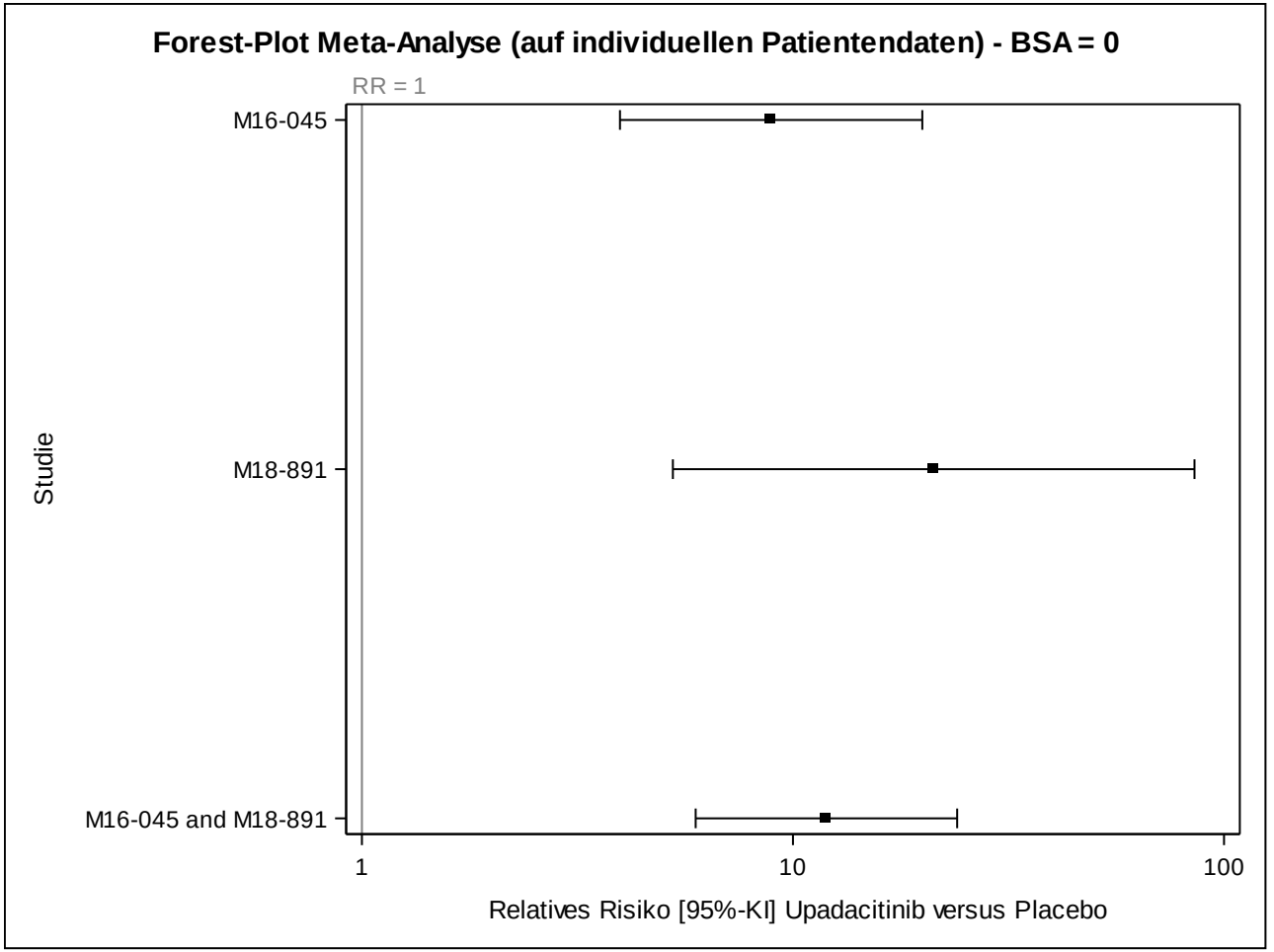


modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

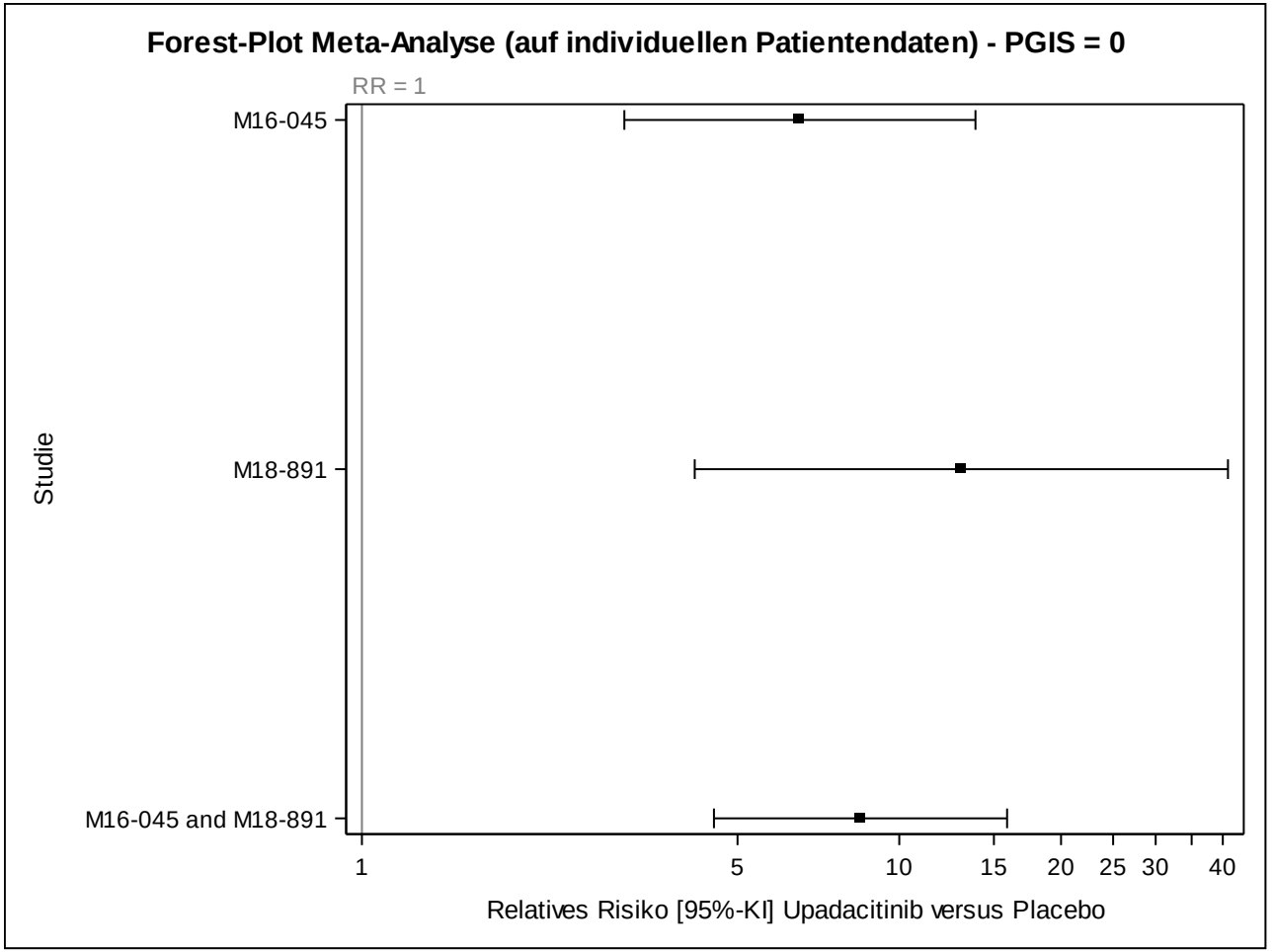


modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Figure 2.5.6
Forest Plot - Body Surface Area (BSA) = 0 (modified NRI-C)
(ITT_M Population)



modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.



modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
Adjusted Relative Risk, CI based on a generalized linear model with treatment, vIGA-AD categories and study as covariates and log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.1
Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	625 (64.3)	276 (57.1)
	Unstratified Analysis		
	Odds Ratio	1.354	
	95% CI	1.083, 1.693	
	p-value	0.0078	
	Relative Risk	1.123	
	95% CI	1.027, 1.229	
	p-value	0.0112	
	Risk Difference	0.071	
	95% CI	0.018, 0.125	
	p-value	0.0086	
	Interaction p-value	0.5680	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.2
Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	621 (63.9)	264 (54.7)
	Unstratified Analysis		
	Odds Ratio	1.472	
	95% CI	1.179, 1.839	
	p-value	0.0007	
	Relative Risk	1.166	
	95% CI	1.062, 1.280	
	p-value	0.0013	
	Risk Difference	0.092	
	95% CI	0.039, 0.146	
	p-value	0.0007	
	Interaction p-value	0.4411	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.3
Serious Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	23 (2.4)	13 (2.7)
	Unstratified Analysis		
	Odds Ratio	0.877	
	95% CI	0.440, 1.747	
	p-value	0.7085	
	Relative Risk	0.880	
	95% CI	0.450, 1.722	
	p-value	0.7088	
	Risk Difference	-0.003	
	95% CI	-0.021, 0.014	
	p-value	0.7017	
	Interaction p-value	0.8611	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.4
Serious Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	23 (2.4)	10 (2.1)
	Unstratified Analysis		
	Odds Ratio	1.147	
	95% CI	0.542, 2.430	
	p-value	0.7201	
	Relative Risk	1.144	
	95% CI	0.549, 2.384	
	p-value	0.7197	
	Risk Difference	0.003	
	95% CI	-0.013, 0.019	
	p-value	0.7420	
	Interaction p-value	0.7147	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.5
Adverse Events of CTCAE Grade >=3
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	52 (5.3)	23 (4.8)
	Unstratified Analysis		
	Odds Ratio	1.132	
	95% CI	0.684, 1.874	
	p-value	0.6290	
	Relative Risk	1.126	
	95% CI	0.698, 1.816	
	p-value	0.6261	
	Risk Difference	0.005	
	95% CI	-0.019, 0.028	
	p-value	0.6945	
	Interaction p-value	0.6579	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.6
Adverse Events of CTCAE Grade >=3 (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	50 (5.1)	16 (3.3)
	Unstratified Analysis		
	Odds Ratio	1.587	
	95% CI	0.894, 2.820	
	p-value	0.1150	
	Relative Risk	1.558	
	95% CI	0.897, 2.704	
	p-value	0.1153	
	Risk Difference	0.016	
	95% CI	-0.005, 0.036	
	p-value	0.1368	
	Interaction p-value	0.5589	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.7
Adverse Events of CTCAE Grade <3
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	616 (63.4)	265 (54.9)
	Unstratified Analysis		
	Odds Ratio	1.427	
	95% CI	1.143, 1.783	
	p-value	0.0017	
	Relative Risk	1.153	
	95% CI	1.050, 1.266	
	p-value	0.0028	
	Risk Difference	0.085	
	95% CI	0.032, 0.139	
	p-value	0.0019	
	Interaction p-value	0.6263	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.8
Adverse Events leading to discontinuation of study drug
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	31 (3.2)	22 (4.6)
	Unstratified Analysis		
	Odds Ratio	0.690	
	95% CI	0.395, 1.206	
	p-value	0.1926	
	Relative Risk	0.700	
	95% CI	0.410, 1.196	
	p-value	0.1919	
	Risk Difference	-0.014	
	95% CI	-0.035, 0.008	
	p-value	0.2154	
	Interaction p-value	0.9239	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.9
Fatal Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.1
Adverse Events of Special Interest - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	6 (0.6)	1 (0.2)
	Unstratified Analysis		
	Odds Ratio	2.991	
	95% CI	0.359, 24.919	
	p-value	0.3110	
	Relative Risk	2.978	
	95% CI	0.360, 24.665	
	p-value	0.3117	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.2624	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.2
Adverse Events of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	6 (0.6)	4 (0.8)
	Unstratified Analysis		
	Odds Ratio	0.745	
	95% CI	0.209, 2.656	
	p-value	0.6504	
	Relative Risk	0.745	
	95% CI	0.211, 2.625	
	p-value	0.6469	
	Risk Difference	0.004	
	95% CI	-0.012, 0.020	
	p-value	0.6190	
	Interaction p-value	0.0486	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.3
Adverse Events of Special Interest - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	17 (1.7)	2 (0.4)
	Unstratified Analysis		
	Odds Ratio	4.278	
	95% CI	0.984, 18.596	
	p-value	0.0525	
	Relative Risk	4.217	
	95% CI	0.978, 18.175	
	p-value	0.0536	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.1225	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.4
Adverse Events of Special Interest - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.5
Adverse Events of Special Interest - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	7 (0.7)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.6
Adverse Events of Special Interest - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	7 (0.7)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.7
Adverse Events of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	4 (0.4)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.8
Adverse Events of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.9
Adverse Events of Special Interest - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	1 (0.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.10
Adverse Events of Special Interest - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	16 (1.6)	6 (1.2)
	Unstratified Analysis		
	Odds Ratio	1.331	
	95% CI	0.518, 3.425	
	p-value	0.5526	
	Relative Risk	1.327	
	95% CI	0.523, 3.369	
	p-value	0.5518	
	Risk Difference	0.003	
	95% CI	-0.010, 0.017	
	p-value	0.6106	
	Interaction p-value	0.2116	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.11
Adverse Events of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.12
Adverse Events of Special Interest - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	11 (1.1)	3 (0.6)
	Unstratified Analysis		
	Odds Ratio	1.830	
	95% CI	0.508, 6.591	
	p-value	0.3553	
	Relative Risk	1.820	
	95% CI	0.510, 6.493	
	p-value	0.3561	
	Risk Difference	0.005	
	95% CI	-0.004, 0.015	
	p-value	0.2722	
	Interaction p-value	0.6963	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.13
Adverse Events of Special Interest - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	20 (2.1)	2 (0.4)
	Unstratified Analysis		
	Odds Ratio	5.097	
	95% CI	1.185, 21.924	
	p-value	0.0287	
	Relative Risk	4.995	
	95% CI	1.174, 21.258	
	p-value	0.0295	
	Risk Difference	0.010	
	95% CI	-0.002, 0.022	
	p-value	0.0965	
	Interaction p-value	0.3679	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.14
Adverse Events of Special Interest - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	4 (0.4)	2 (0.4)
	Unstratified Analysis		
	Odds Ratio	0.998	
	95% CI	0.182, 5.476	
	p-value	0.9981	
	Relative Risk	0.997	
	95% CI	0.183, 5.413	
	p-value	0.9968	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.3425	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.15
Adverse Events of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	41 (4.2)	9 (1.9)
	Unstratified Analysis		
	Odds Ratio	2.322	
	95% CI	1.119, 4.819	
	p-value	0.0237	
	Relative Risk	2.266	
	95% CI	1.110, 4.622	
	p-value	0.0246	
	Risk Difference	0.023	
	95% CI	0.006, 0.040	
	p-value	0.0092	
	Interaction p-value	0.9627	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.16
Adverse Events of Special Interest - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.17
Adverse Events of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.18
Adverse Events of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.1
Serious Adverse Event of Special Interest - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	6 (0.6)	1 (0.2)
	Unstratified Analysis		
	Odds Ratio	2.991	
	95% CI	0.359, 24.919	
	p-value	0.3110	
	Relative Risk	2.978	
	95% CI	0.360, 24.665	
	p-value	0.3117	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.2624	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.2
Serious Adverse Event of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	1 (0.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.3
Serious Adverse Event of Special Interest - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.4
Serious Adverse Event of Special Interest - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.5
Serious Adverse Event of Special Interest - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.6
Serious Adverse Event of Special Interest - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.7
Serious Adverse Event of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.8
Serious Adverse Event of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.9
Serious Adverse Event of Special Interest - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.10
Serious Adverse Event of Special Interest - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.11
Serious Adverse Event of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.12
Serious Adverse Event of Special Interest - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.13
Serious Adverse Event of Special Interest - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.14
Serious Adverse Event of Special Interest - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.15
Serious Adverse Event of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.16
Serious Adverse Event of Special Interest - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.17
Serious Adverse Event of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.18
Serious Adverse Event of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.1
Adverse Events of Special Interest of CTCAE Grade >=3 - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	5 (0.5)	1 (0.2)
	Unstratified Analysis		
	Odds Ratio	2.488	
	95% CI	0.290, 21.362	
	p-value	0.4060	
	Relative Risk	2.478	
	95% CI	0.290, 21.145	
	p-value	0.4068	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.3381	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.2
Adverse Events of Special Interest of CTCAE Grade >=3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	1 (0.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.3
Adverse Events of Special Interest of CTCAE Grade >=3 - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	2 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.4
Adverse Events of Special Interest of CTCAE Grade >=3 - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.5
Adverse Events of Special Interest of CTCAE Grade >=3 - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.6
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.7
Adverse Events of Special Interest of CTCAE Grade >=3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	1 (0.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.8
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	2 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.9
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.10
Adverse Events of Special Interest of CTCAE Grade >=3 - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.11
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.12
Adverse Events of Special Interest of CTCAE Grade >=3 - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.13
Adverse Events of Special Interest of CTCAE Grade >=3 - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.14
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	1 (0.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.15
Adverse Events of Special Interest of CTCAE Grade >=3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	8 (0.8)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.16
Adverse Events of Special Interest of CTCAE Grade >=3 - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.17
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.18
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.1
Adverse Events of Special Interest of CTCAE Grade <3 - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	1 (0.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.2
Adverse Events of Special Interest of CTCAE Grade <3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	6 (0.6)	4 (0.8)
	Unstratified Analysis		
	Odds Ratio	0.745	
	95% CI	0.209, 2.656	
	p-value	0.6504	
	Relative Risk	0.745	
	95% CI	0.211, 2.625	
	p-value	0.6469	
	Risk Difference	0.004	
	95% CI	-0.012, 0.020	
	p-value	0.6190	
	Interaction p-value	0.0486	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.3
Adverse Events of Special Interest of CTCAE Grade <3 - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	15 (1.5)	2 (0.4)
	Unstratified Analysis		
	Odds Ratio	3.767	
	95% CI	0.858, 16.541	
	p-value	0.0789	
	Relative Risk	3.720	
	95% CI	0.854, 16.199	
	p-value	0.0801	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	0.1264	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.4
Adverse Events of Special Interest of CTCAE Grade <3 - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.5
Adverse Events of Special Interest of CTCAE Grade <3 - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	4 (0.4)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.6
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	4 (0.4)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.7
Adverse Events of Special Interest of CTCAE Grade <3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.8
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	1 (0.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.9
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	1 (0.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.10
Adverse Events of Special Interest of CTCAE Grade <3 - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	13 (1.3)	6 (1.2)
	Unstratified Analysis		
	Odds Ratio	1.077	
	95% CI	0.407, 2.852	
	p-value	0.8807	
	Relative Risk	1.076	
	95% CI	0.412, 2.814	
	p-value	0.8812	
	Risk Difference	0.001	
	95% CI	-0.011, 0.014	
	p-value	0.8449	
	Interaction p-value	0.3916	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.11
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.12
Adverse Events of Special Interest of CTCAE Grade <3 - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	11 (1.1)	3 (0.6)
	Unstratified Analysis		
	Odds Ratio	1.830	
	95% CI	0.508, 6.591	
	p-value	0.3553	
	Relative Risk	1.820	
	95% CI	0.510, 6.493	
	p-value	0.3561	
	Risk Difference	0.005	
	95% CI	-0.004, 0.015	
	p-value	0.2722	
	Interaction p-value	0.6963	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.13
Adverse Events of Special Interest of CTCAE Grade <3 - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	17 (1.7)	2 (0.4)
	Unstratified Analysis		
	Odds Ratio	4.317	
	95% CI	0.992, 18.790	
	p-value	0.0513	
	Relative Risk	4.248	
	95% CI	0.987, 18.286	
	p-value	0.0521	
	Risk Difference	0.007	
	95% CI	-0.004, 0.018	
	p-value	0.2019	
	Interaction p-value	0.3275	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Table 3.1.13.14
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	3 (0.3)	2 (0.4)
	Unstratified Analysis		
	Odds Ratio	0.748	
	95% CI	0.124, 4.509	
	p-value	0.7518	
	Relative Risk	0.750	
	95% CI	0.126, 4.459	
	p-value	0.7518	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Table 3.1.13.15
Adverse Events of Special Interest of CTCAE Grade <3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	36 (3.7)	9 (1.9)
	Unstratified Analysis		
	Odds Ratio	2.027	
	95% CI	0.968, 4.243	
	p-value	0.0609	
	Relative Risk	1.988	
	95% CI	0.966, 4.094	
	p-value	0.0621	
	Risk Difference	0.018	
	95% CI	0.002, 0.035	
	p-value	0.0324	
	Interaction p-value	0.8930	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.16
Adverse Events of Special Interest of CTCAE Grade <3 - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.17
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.18
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	
	Interaction p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.2.1
Incidence of Adverse Events leading to discontinuation of study drug by SOC and PT
(Safety Analysis Set)

Up to Visit	System Organ Class (SOC) Preferred Term (PT)	Upadacitinib (N=972) n (%)	Placebo (N=483) n (%)
Week 16	Skin and subcutaneous tissue disorders	11 (1.1)	15 (3.1)
	Dermatitis atopic	5 (0.5)	11 (2.3)
	Eczema	1 (0.1)	2 (0.4)
	Acne	2 (0.2)	0 (0.0)
	Erythema	1 (0.1)	1 (0.2)
	Dermatitis exfoliative generalised	0 (0.0)	1 (0.2)
	Parapsoriasis	1 (0.1)	0 (0.0)
	Urticaria	1 (0.1)	0 (0.0)
	Infections and infestations	6 (0.6)	2 (0.4)
	Bursitis infective staphylococcal	1 (0.1)	0 (0.0)
	Cellulitis	0 (0.0)	1 (0.2)
	Eye infection	1 (0.1)	0 (0.0)
	Gastroenteritis	0 (0.0)	1 (0.2)
	Herpes ophthalmic	1 (0.1)	0 (0.0)
	Orchitis	1 (0.1)	0 (0.0)
	Pharyngeal abscess	1 (0.1)	0 (0.0)
	Sinusitis	1 (0.1)	0 (0.0)
	Gastrointestinal disorders	3 (0.3)	0 (0.0)
	Flatulence	1 (0.1)	0 (0.0)
	Gastrooesophageal reflux disease	1 (0.1)	0 (0.0)
	Nausea	1 (0.1)	0 (0.0)
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.3)	0 (0.0)
	Anal squamous cell carcinoma	1 (0.1)	0 (0.0)
	Gastric cancer	1 (0.1)	0 (0.0)
	Invasive ductal breast carcinoma	1 (0.1)	0 (0.0)
	Nervous system disorders	2 (0.2)	1 (0.2)
	Headache	2 (0.2)	0 (0.0)
	Disturbance in attention	1 (0.1)	0 (0.0)
	Dizziness	1 (0.1)	0 (0.0)
	Migraine	0 (0.0)	1 (0.2)
	Psychiatric disorders	2 (0.2)	1 (0.2)
	Anxiety	1 (0.1)	1 (0.2)
	Bipolar disorder	1 (0.1)	0 (0.0)
	Suicide attempt	1 (0.1)	0 (0.0)
	General disorders and administration site conditions	2 (0.2)	0 (0.0)
	Face oedema	1 (0.1)	0 (0.0)
	Feeling jittery	1 (0.1)	0 (0.0)
	Investigations	2 (0.2)	0 (0.0)
	Blood creatine phosphokinase increased	1 (0.1)	0 (0.0)
	Haemoglobin decreased	1 (0.1)	0 (0.0)
	Musculoskeletal and connective tissue disorders	1 (0.1)	1 (0.2)
	Myopathy	0 (0.0)	1 (0.2)
	Rhabdomyolysis	1 (0.1)	0 (0.0)
	Blood and lymphatic system disorders	1 (0.1)	0 (0.0)
	Neutropenia	1 (0.1)	0 (0.0)

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.1 coding dictionary applied.
N: Number of subjects, n: Number of subjects with event
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.2.1
Incidence of Adverse Events leading to discontinuation of study drug by SOC and PT
(Safety Analysis Set)

Up to Visit	System Organ Class (SOC) Preferred Term (PT)	Upadacitinib (N=972) n (%)	Placebo (N=483) n (%)
Week 16	Immune system disorders	0 (0.0)	1 (0.2)
	Drug hypersensitivity	0 (0.0)	1 (0.2)
	Metabolism and nutrition disorders	1 (0.1)	0 (0.0)
	Decreased appetite	1 (0.1)	0 (0.0)
	Respiratory, thoracic and mediastinal disorders	0 (0.0)	1 (0.2)
	Pulmonary embolism	0 (0.0)	1 (0.2)

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.1 coding dictionary applied.
N: Number of subjects, n: Number of subjects with event
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Blood and lymphatic system disorders	Week 16	Number of subjects with events, n (%)	34 (3.5)	10 (2.1)
		Unstratified Analysis		
		Odds Ratio	1.716	
		95% CI	0.840, 3.503	
		p-value	0.1382	
		Relative Risk	1.691	
		95% CI	0.843, 3.393	
		p-value	0.1393	
		Risk Difference	0.014	
		95% CI	-0.003, 0.03	
		p-value	0.1131	
		Interaction p-value	0.7269	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Blood and lymphatic system disorders - PT:Neutropenia	Week 16	Number of subjects with events, n (%)	15 (1.5)	1 (0.2)
		Unstratified Analysis		
		Odds Ratio	7.626	
		95% CI	1.003, 57.977	
		p-value	0.0496	
		Relative Risk	7.507	
		95% CI	0.996, 56.595	
		p-value	0.0505	
		Risk Difference	0.006	
		95% CI	-0.006, 0.01	
		p-value	0.3164	
		Interaction p-value	0.0547	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Ear and labyrinth disorders	Week 16	Number of subjects with events, n (%)	7 (0.7)	10 (2.1)
		Unstratified Analysis		
		Odds Ratio	0.341	
		95% CI	0.129, 0.904	
		p-value	0.0305	
		Relative Risk	0.347	
		95% CI	0.133, 0.905	
		p-value	0.0305	
		Risk Difference	-0.012	
		95% CI	-0.026, 0.00	
		p-value	0.0784	
		Interaction p-value	0.9581	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Eye disorders	Week 16	Number of subjects with events, n (%)	24 (2.5)	16 (3.3)
		Unstratified Analysis		
		Odds Ratio	0.739	
		95% CI	0.389, 1.405	
		p-value	0.3559	
		Relative Risk	0.745	
		95% CI	0.400, 1.390	
		p-value	0.3553	
		Risk Difference	-0.008	
		95% CI	-0.027, 0.01	
		p-value	0.3763	
		Interaction p-value	0.5244	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Gastrointestinal disorders	Week 16	Number of subjects with events, n (%)	122 (12.6)	36 (7.5)
		Unstratified Analysis		
		Odds Ratio	1.786	
		95% CI	1.210, 2.637	
		p-value	0.0035	
		Relative Risk	1.683	
		95% CI	1.180, 2.400	
		p-value	0.0040	
		Risk Difference	0.051	
		95% CI	0.020, 0.082	
		p-value	0.0011	
		Interaction p-value	0.5712	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Gastrointestinal disorders - PT:Diarrhoea	Week 16	Number of subjects with events, n (%)	31 (3.2)	14 (2.9)
		Unstratified Analysis		
		Odds Ratio	1.104	
		95% CI	0.581, 2.094	
		p-value	0.7632	
		Relative Risk	1.100	
		95% CI	0.591, 2.049	
		p-value	0.7633	
		Risk Difference	0.003	
		95% CI	-0.016, 0.02	
		p-value	0.7605	
		Interaction p-value	0.9344	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Gastrointestinal disorders - PT:Nausea	Week 16	Number of subjects with events, n (%)	27 (2.8)	4 (0.8)
		Unstratified Analysis		
		Odds Ratio	3.434	
		95% CI	1.194, 9.876	
		p-value	0.0221	
		Relative Risk	3.364	
		95% CI	1.184, 9.555	
		p-value	0.0227	
		Risk Difference	0.017	
		95% CI	0.003, 0.031	
		p-value	0.0151	
		Interaction p-value	0.5139	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: General disorders and administration site conditions	Week 16	Number of subjects with events, n (%)	62 (6.4)	22 (4.6)
		Unstratified Analysis		
		Odds Ratio	1.428	
		95% CI	0.867, 2.353	
		p-value	0.1616	
		Relative Risk	1.401	
		95% CI	0.872, 2.250	
		p-value	0.1635	
		Risk Difference	0.018	
		95% CI	-0.006, 0.04	
		p-value	0.1351	
		Interaction p-value	0.8278	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: General disorders and administration site conditions - PT:Fatigue	Week 16	Number of subjects with events, n (%)	16 (1.6)	5 (1.0)
		Unstratified Analysis		
		Odds Ratio	1.599	
		95% CI	0.582, 4.391	
		p-value	0.3626	
		Relative Risk	1.590	
		95% CI	0.586, 4.314	
		p-value	0.3625	
		Risk Difference	0.005	
		95% CI	-0.007, 0.01	
		p-value	0.3902	
		Interaction p-value	0.3802	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: General disorders and administration site conditions - PT:Influenza like illness	Week 16	Number of subjects with events, n (%)	15 (1.5)	4 (0.8)
		Unstratified Analysis		
		Odds Ratio	1.879	
		95% CI	0.620, 5.694	
		p-value	0.2647	
		Relative Risk	1.864	
		95% CI	0.622, 5.585	
		p-value	0.2660	
		Risk Difference	0.008	
		95% CI	-0.003, 0.01	
		p-value	0.1506	
		Interaction p-value	0.4286	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: General disorders and administration site conditions - PT:Pyrexia	Week 16	Number of subjects with events, n (%)	17 (1.7)	5 (1.0)
		Unstratified Analysis		
		Odds Ratio	1.702	
		95% CI	0.624, 4.641	
		p-value	0.2989	
		Relative Risk	1.690	
		95% CI	0.627, 4.552	
		p-value	0.2997	
		Risk Difference	0.007	
		95% CI	-0.005, 0.02	
		p-value	0.2475	
		Interaction p-value	0.6164	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations	Week 16	Number of subjects with events, n (%)	364 (37.4)	132 (27.3)
		Unstratified Analysis		
		Odds Ratio	1.600	
		95% CI	1.259, 2.033	
		p-value	0.0001	
		Relative Risk	1.381	
		95% CI	1.170, 1.630	
		p-value	0.0001	
		Risk Difference	0.098	
		95% CI	0.048, 0.147	
		p-value	0.0001	
		Interaction p-value	0.1262	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Folliculitis	Week 16	Number of subjects with events, n (%)	26 (2.7)	7 (1.4)
		Unstratified Analysis		
		Odds Ratio	1.869	
		95% CI	0.805, 4.336	
		p-value	0.1455	
		Relative Risk	1.846	
		95% CI	0.807, 4.222	
		p-value	0.1465	
		Risk Difference	0.013	
		95% CI	-0.002, 0.02	
		p-value	0.0991	
		Interaction p-value	0.1672	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Gastroenteritis	Week 16	Number of subjects with events, n (%)	10 (1.0)	5 (1.0)
		Unstratified Analysis		
		Odds Ratio	0.994	
		95% CI	0.338, 2.925	
		p-value	0.9916	
		Relative Risk	0.994	
		95% CI	0.342, 2.892	
		p-value	0.9914	
		Risk Difference	0.000	
		95% CI	-0.011, 0.01	
		p-value	0.9878	
		Interaction p-value	0.7207	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Herpes simplex	Week 16	Number of subjects with events, n (%)	18 (1.9)	4 (0.8)
		Unstratified Analysis		
		Odds Ratio	2.265	
		95% CI	0.762, 6.734	
		p-value	0.1413	
		Relative Risk	2.238	
		95% CI	0.762, 6.574	
		p-value	0.1428	
		Risk Difference	0.010	
		95% CI	-0.001, 0.02	
		p-value	0.0669	
		Interaction p-value	0.5987	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Herpes zoster	Week 16	Number of subjects with events, n (%)	17 (1.7)	2 (0.4)
		Unstratified Analysis		
		Odds Ratio	4.278	
		95% CI	0.984, 18.596	
		p-value	0.0525	
		Relative Risk	4.217	
		95% CI	0.978, 18.175	
		p-value	0.0536	
		Risk Difference	NE	
		95% CI	NE, NE	
		p-value	NE	
		Interaction p-value	0.1225	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Influenza	Week 16	Number of subjects with events, n (%)	10 (1.0)	1 (0.2)
		Unstratified Analysis		
		Odds Ratio	5.008	
		95% CI	0.639, 39.236	
		p-value	0.1251	
		Relative Risk	4.965	
		95% CI	0.637, 38.676	
		p-value	0.1260	
		Risk Difference	NE	
		95% CI	NE, NE	
		p-value	NE	
		Interaction p-value	0.2526	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Nasopharyngitis	Week 16	Number of subjects with events, n (%)	79 (8.1)	26 (5.4)
		Unstratified Analysis		
		Odds Ratio	1.559	
		95% CI	0.986, 2.464	
		p-value	0.0574	
		Relative Risk	1.512	
		95% CI	0.985, 2.323	
		p-value	0.0588	
		Risk Difference	0.026	
		95% CI	0.000, 0.052	
		p-value	0.0497	
		Interaction p-value	0.8458	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Oral herpes	Week 16	Number of subjects with events, n (%)	34 (3.5)	4 (0.8)
		Unstratified Analysis		
		Odds Ratio	4.343	
		95% CI	1.532, 12.310	
		p-value	0.0057	
		Relative Risk	4.224	
		95% CI	1.508, 11.834	
		p-value	0.0061	
		Risk Difference	0.027	
		95% CI	0.014, 0.041	
		p-value	<.0001	
		Interaction p-value	0.3351	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Upper respiratory tract infection	Week 16	Number of subjects with events, n (%)	78 (8.0)	28 (5.8)
		Unstratified Analysis		
		Odds Ratio	1.424	
		95% CI	0.910, 2.227	
		p-value	0.1220	
		Relative Risk	1.389	
		95% CI	0.916, 2.107	
		p-value	0.1217	
		Risk Difference	0.019	
		95% CI	-0.007, 0.04	
		p-value	0.1560	
		Interaction p-value	0.6301	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Urinary tract infection	Week 16	Number of subjects with events, n (%)	13 (1.3)	11 (2.3)
		Unstratified Analysis		
		Odds Ratio	0.581	
		95% CI	0.258, 1.308	
		p-value	0.1896	
		Relative Risk	0.586	
		95% CI	0.265, 1.298	
		p-value	0.1880	
		Risk Difference	-0.010	
		95% CI	-0.027, 0.00	
		p-value	0.2181	
		Interaction p-value	0.0090	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations - PT:Viral upper respiratory tract infection	Week 16	Number of subjects with events, n (%)	11 (1.1)	2 (0.4)
		Unstratified Analysis		
		Odds Ratio	2.782	
		95% CI	0.612, 12.639	
		p-value	0.1851	
		Relative Risk	2.745	
		95% CI	0.613, 12.301	
		p-value	0.1869	
		Risk Difference	NE	
		95% CI	NE, NE	
		p-value	NE	
		Interaction p-value	0.5567	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Injury, poisoning and procedural complications	Week 16	Number of subjects with events, n (%)	37 (3.8)	14 (2.9)
		Unstratified Analysis		
		Odds Ratio	1.326	
		95% CI	0.710, 2.478	
		p-value	0.3758	
		Relative Risk	1.315	
		95% CI	0.718, 2.408	
		p-value	0.3757	
		Risk Difference	0.009	
		95% CI	-0.011, 0.02	
		p-value	0.3846	
		Interaction p-value	0.3566	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Investigations	Week 16	Number of subjects with events, n (%)	93 (9.6)	27 (5.6)
		Unstratified Analysis		
		Odds Ratio	1.792	
		95% CI	1.150, 2.793	
		p-value	0.0100	
		Relative Risk	1.718	
		95% CI	1.136, 2.599	
		p-value	0.0104	
		Risk Difference	0.036	
		95% CI	0.009, 0.064	
		p-value	0.0097	
		Interaction p-value	0.3515	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Investigations - PT:Blood creatine phosphokinase increased	Week 16	Number of subjects with events, n (%)	41 (4.2)	9 (1.9)
		Unstratified Analysis		
		Odds Ratio	2.322	
		95% CI	1.119, 4.819	
		p-value	0.0237	
		Relative Risk	2.266	
		95% CI	1.110, 4.622	
		p-value	0.0246	
		Risk Difference	0.023	
		95% CI	0.006, 0.040	
		p-value	0.0092	
		Interaction p-value	0.9627	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Investigations - PT:Weight increased	Week 16	Number of subjects with events, n (%)	18 (1.9)	1 (0.2)
		Unstratified Analysis		
		Odds Ratio	9.121	
		95% CI	1.214, 68.544	
		p-value	0.0317	
		Relative Risk	8.969	
		95% CI	1.201, 66.972	
		p-value	0.0325	
		Risk Difference	NE	
		95% CI	NE, NE	
		p-value	NE	
		Interaction p-value	0.1459	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Metabolism and nutrition disorders	Week 16	Number of subjects with events, n (%)	29 (3.0)	13 (2.7)
		Unstratified Analysis		
		Odds Ratio	1.113	
		95% CI	0.573, 2.162	
		p-value	0.7512	
		Relative Risk	1.112	
		95% CI	0.584, 2.119	
		p-value	0.7463	
		Risk Difference	0.001	
		95% CI	-0.017, 0.01	
		p-value	0.9334	
		Interaction p-value	0.2259	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Musculoskeletal and connective tissue disorders	Week 16	Number of subjects with events, n (%)	62 (6.4)	33 (6.8)
		Unstratified Analysis		
		Odds Ratio	0.930	
		95% CI	0.600, 1.440	
		p-value	0.7441	
		Relative Risk	0.932	
		95% CI	0.620, 1.401	
		p-value	0.7336	
		Risk Difference	-0.002	
		95% CI	-0.029, 0.02	
		p-value	0.8850	
		Interaction p-value	0.1111	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Musculoskeletal and connective tissue disorders - PT:Arthralgia	Week 16	Number of subjects with events, n (%)	12 (1.2)	5 (1.0)
		Unstratified Analysis		
		Odds Ratio	1.195	
		95% CI	0.419, 3.413	
		p-value	0.7387	
		Relative Risk	1.193	
		95% CI	0.423, 3.367	
		p-value	0.7390	
		Risk Difference	0.002	
		95% CI	-0.009, 0.01	
		p-value	0.7113	
		Interaction p-value	0.7129	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Musculoskeletal and connective tissue disorders - PT:Back pain	Week 16	Number of subjects with events, n (%)	15 (1.5)	10 (2.1)
		Unstratified Analysis		
		Odds Ratio	0.743	
		95% CI	0.331, 1.668	
		p-value	0.4711	
		Relative Risk	0.744	
		95% CI	0.337, 1.641	
		p-value	0.4632	
		Risk Difference	0.001	
		95% CI	-0.014, 0.01	
		p-value	0.9073	
		Interaction p-value	0.0858	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Musculoskeletal and connective tissue disorders - PT:Myalgia	Week 16	Number of subjects with events, n (%)	17 (1.7)	3 (0.6)
		Unstratified Analysis		
		Odds Ratio	2.850	
		95% CI	0.831, 9.775	
		p-value	0.0957	
		Relative Risk	2.817	
		95% CI	0.830, 9.565	
		p-value	0.0968	
		Risk Difference	0.011	
		95% CI	0.001, 0.022	
		p-value	0.0347	
		Interaction p-value	0.6619	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Week 16	Number of subjects with events, n (%)	12 (1.2)	3 (0.6)
		Unstratified Analysis		
		Odds Ratio	1.999	
		95% CI	0.562, 7.119	
		p-value	0.2850	
		Relative Risk	1.987	
		95% CI	0.563, 7.007	
		p-value	0.2858	
		Risk Difference	0.006	
		95% CI	-0.003, 0.01	
		p-value	0.2023	
		Interaction p-value	0.5934	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Nervous system disorders	Week 16	Number of subjects with events, n (%)	84 (8.6)	27 (5.6)
		Unstratified Analysis		
		Odds Ratio	1.598	
		95% CI	1.021, 2.501	
		p-value	0.0404	
		Relative Risk	1.546	
		95% CI	1.016, 2.352	
		p-value	0.0419	
		Risk Difference	0.031	
		95% CI	0.004, 0.058	
		p-value	0.0251	
		Interaction p-value	0.2886	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Nervous system disorders - PT:Headache	Week 16	Number of subjects with events, n (%)	61 (6.3)	20 (4.1)
		Unstratified Analysis		
		Odds Ratio	1.550	
		95% CI	0.924, 2.600	
		p-value	0.0970	
		Relative Risk	1.515	
		95% CI	0.926, 2.481	
		p-value	0.0985	
		Risk Difference	0.021	
		95% CI	-0.002, 0.04	
		p-value	0.0775	
		Interaction p-value	0.7628	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Psychiatric disorders	Week 16	Number of subjects with events, n (%)	21 (2.2)	13 (2.7)
		Unstratified Analysis		
		Odds Ratio	0.798	
		95% CI	0.396, 1.608	
		p-value	0.5280	
		Relative Risk	0.802	
		95% CI	0.405, 1.588	
		p-value	0.5269	
		Risk Difference	-0.005	
		95% CI	-0.022, 0.01	
		p-value	0.5652	
		Interaction p-value	0.4120	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Renal and urinary disorders	Week 16	Number of subjects with events, n (%)	13 (1.3)	5 (1.0)
		Unstratified Analysis		
		Odds Ratio	1.298	
		95% CI	0.460, 3.663	
		p-value	0.6222	
		Relative Risk	1.296	
		95% CI	0.465, 3.613	
		p-value	0.6204	
		Risk Difference	0.001	
		95% CI	-0.010, 0.01	
		p-value	0.8107	
		Interaction p-value	0.2508	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Reproductive system and breast disorders	Week 16	Number of subjects with events, n (%)	13 (1.3)	5 (1.0)
		Unstratified Analysis		
		Odds Ratio	1.299	
		95% CI	0.460, 3.668	
		p-value	0.6212	
		Relative Risk	1.290	
		95% CI	0.463, 3.595	
		p-value	0.6262	
		Risk Difference	NE	
		95% CI	NE, NE	
		p-value	NE	
		Interaction p-value	0.0259	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Respiratory, thoracic and mediastinal disorders	Week 16	Number of subjects with events, n (%)	67 (6.9)	27 (5.6)
		Unstratified Analysis		
		Odds Ratio	1.251	
		95% CI	0.789, 1.983	
		p-value	0.3415	
		Relative Risk	1.233	
		95% CI	0.799, 1.901	
		p-value	0.3437	
		Risk Difference	0.014	
		95% CI	-0.013, 0.04	
		p-value	0.3088	
		Interaction p-value	0.3101	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Respiratory, thoracic and mediastinal disorders - PT:Cough	Week 16	Number of subjects with events, n (%)	27 (2.8)	8 (1.7)
		Unstratified Analysis		
		Odds Ratio	1.695	
		95% CI	0.764, 3.761	
		p-value	0.1941	
		Relative Risk	1.676	
		95% CI	0.768, 3.662	
		p-value	0.1949	
		Risk Difference	0.011	
		95% CI	-0.005, 0.02	
		p-value	0.1794	
		Interaction p-value	0.6511	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Respiratory, thoracic and mediastinal disorders - PT:Oropharyngeal pain	Week 16	Number of subjects with events, n (%)	18 (1.9)	6 (1.2)
		Unstratified Analysis		
		Odds Ratio	1.500	
		95% CI	0.592, 3.804	
		p-value	0.3930	
		Relative Risk	1.491	
		95% CI	0.596, 3.732	
		p-value	0.3936	
		Risk Difference	0.006	
		95% CI	-0.007, 0.02	
		p-value	0.3524	
		Interaction p-value	0.3323	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Skin and subcutaneous tissue disorders	Week 16	Number of subjects with events, n (%)	221 (22.7)	91 (18.8)
		Unstratified Analysis		
		Odds Ratio	1.268	
		95% CI	0.965, 1.665	
		p-value	0.0887	
		Relative Risk	1.207	
		95% CI	0.970, 1.501	
		p-value	0.0915	
		Risk Difference	0.039	
		95% CI	-0.005, 0.08	
		p-value	0.0811	
		Interaction p-value	0.5996	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Skin and subcutaneous tissue disorders - PT:Acne	Week 16	Number of subjects with events, n (%)	122 (12.6)	11 (2.3)
		Unstratified Analysis		
		Odds Ratio	6.163	
		95% CI	3.291, 11.541	
		p-value	<.0001	
		Relative Risk	5.512	
		95% CI	3.003, 10.115	
		p-value	<.0001	
		Risk Difference	0.102	
		95% CI	0.077, 0.127	
		p-value	<.0001	
		Interaction p-value	0.4848	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Skin and subcutaneous tissue disorders - PT:Dermatitis acneiform	Week 16	Number of subjects with events, n (%)	10 (1.0)	0 (0.0)
		Unstratified Analysis		
		Odds Ratio	NE	
		95% CI	NE, NE	
		p-value	NE	
		Relative Risk	NE	
		95% CI	NE, NE	
		p-value	NE	
		Risk Difference	NE	
		95% CI	NE, NE	
		p-value	NE	
		Interaction p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Skin and subcutaneous tissue disorders - PT:Dermatitis atopic	Week 16	Number of subjects with events, n (%)	21 (2.2)	43 (8.9)
		Unstratified Analysis		
		Odds Ratio	0.226	
		95% CI	0.132, 0.385	
		p-value	<.0001	
		Relative Risk	0.243	
		95% CI	0.146, 0.405	
		p-value	<.0001	
		Risk Difference	-0.067	
		95% CI	-0.094, -0.04	
		p-value	<.0001	
		Interaction p-value	0.8994	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Skin and subcutaneous tissue disorders - PT:Pruritus	Week 16	Number of subjects with events, n (%)	8 (0.8)	10 (2.1)
		Unstratified Analysis		
		Odds Ratio	0.391	
		95% CI	0.153, 0.998	
		p-value	0.0496	
		Relative Risk	0.396	
		95% CI	0.158, 0.997	
		p-value	0.0493	
		Risk Difference	-0.011	
		95% CI	-0.025, 0.00	
		p-value	0.1128	
		Interaction p-value	0.7268	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Skin and subcutaneous tissue disorders - PT:Urticaria	Week 16	Number of subjects with events, n (%)	10 (1.0)	3 (0.6)
		Unstratified Analysis		
		Odds Ratio	1.664	
		95% CI	0.456, 6.075	
		p-value	0.4408	
		Relative Risk	1.657	
		95% CI	0.458, 5.992	
		p-value	0.4414	
		Risk Difference	0.004	
		95% CI	-0.005, 0.01	
		p-value	0.3649	
		Interaction p-value	0.6134	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Vascular disorders	Week 16	Number of subjects with events, n (%)	17 (1.7)	10 (2.1)
		Unstratified Analysis		
		Odds Ratio	0.841	
		95% CI	0.382, 1.852	
		p-value	0.6679	
		Relative Risk	0.846	
		95% CI	0.390, 1.833	
		p-value	0.6709	
		Risk Difference	-0.005	
		95% CI	-0.021, 0.01	
		p-value	0.5075	
		Interaction p-value	0.0381	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Vascular disorders - PT:Hypertension	Week 16	Number of subjects with events, n (%)	10 (1.0)	5 (1.0)
		Unstratified Analysis		
		Odds Ratio	0.994	
		95% CI	0.338, 2.925	
		p-value	0.9916	
		Relative Risk	0.993	
		95% CI	0.341, 2.890	
		p-value	0.9900	
		Risk Difference	0.002	
		95% CI	-0.014, 0.01	
		p-value	0.8052	
		Interaction p-value	0.0035	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.2
Frequent Serious Adverse Events by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

!!! There are no Observations for this Report !!!

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.3
Frequent Adverse Events of CTCAE Grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

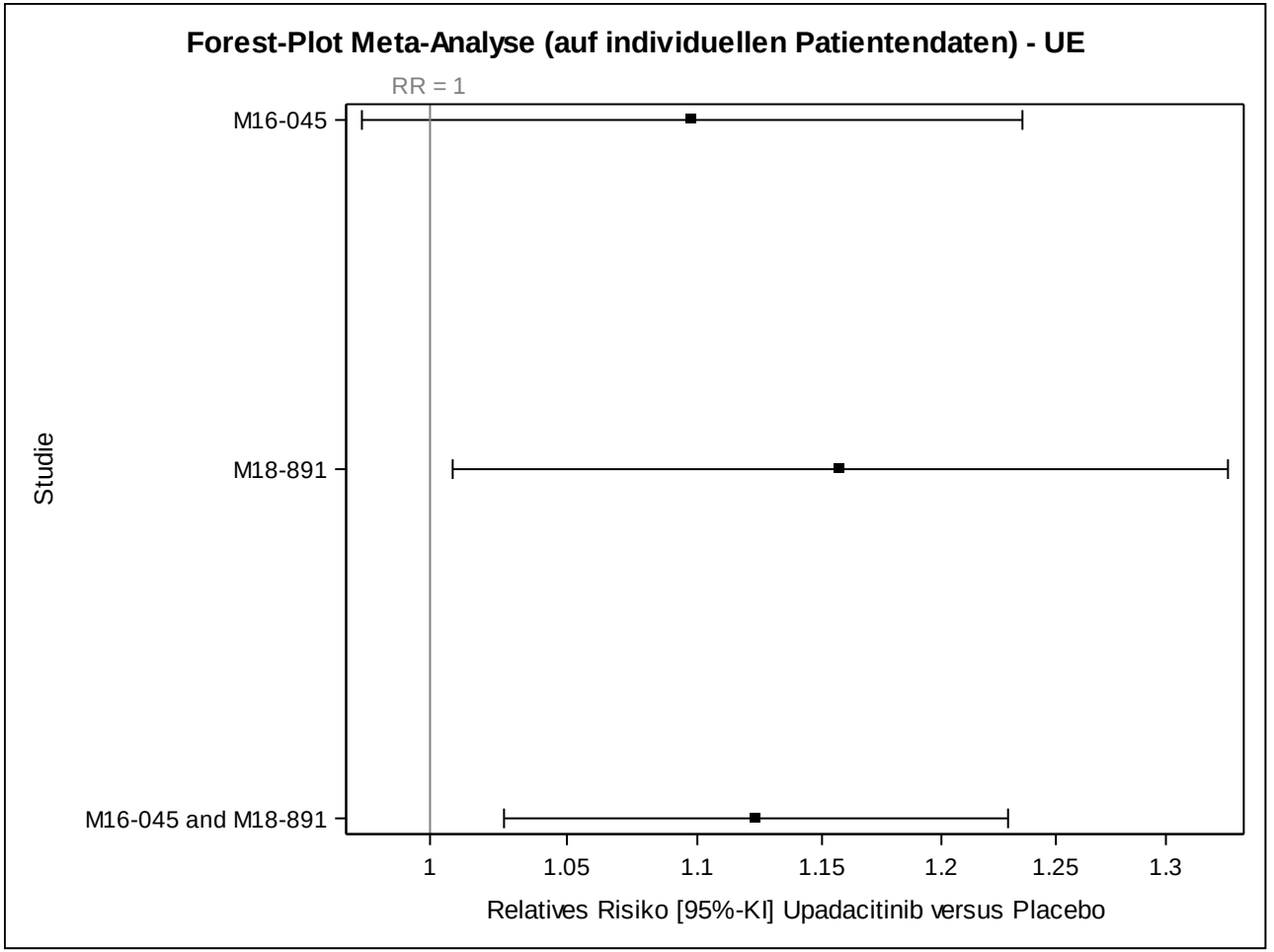
SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Infections and infestations	Week 16	Number of subjects with events, n (%)	13 (1.3)	3 (0.6)
		Unstratified Analysis		
		Odds Ratio	2.169	
		95% CI	0.615, 7.648	
		p-value	0.2285	
		Relative Risk	2.153	
		95% CI	0.617, 7.521	
		p-value	0.2293	
		Risk Difference	0.007	
		95% CI	-0.003, 0.01	
		p-value	0.1564	
		Interaction p-value	0.5108	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

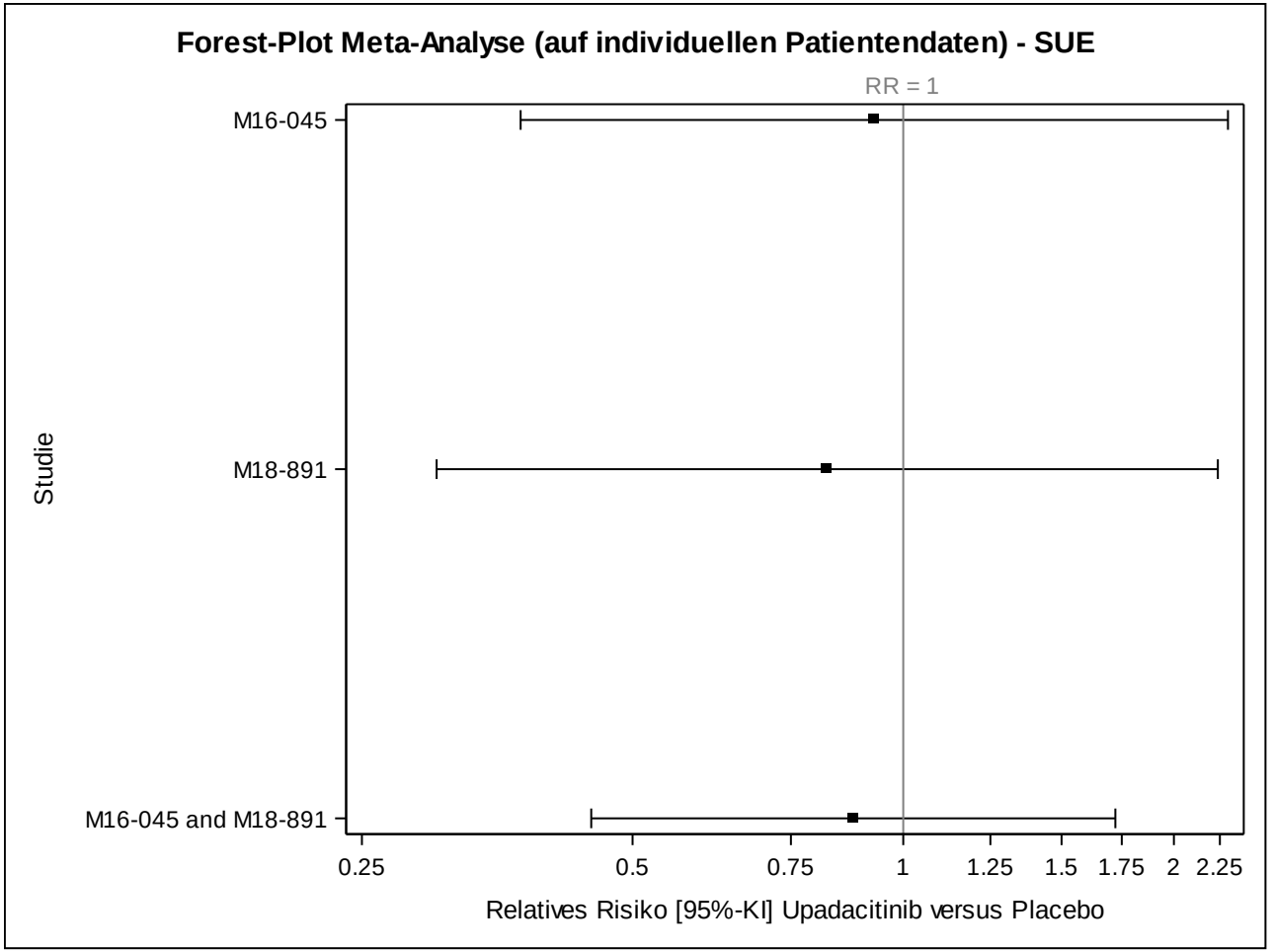
Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.3
Frequent Adverse Events of CTCAE Grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib (N=972)	Placebo (N=483)
SOC: Skin and subcutaneous tissue disorders	Week 16	Number of subjects with events, n (%)	8 (0.8)	12 (2.5)
		Unstratified Analysis		
		Odds Ratio	0.326	
		95% CI	0.132, 0.802	
		p-value	0.0147	
		Relative Risk	0.331	
		95% CI	0.136, 0.805	
		p-value	0.0147	
		Risk Difference	-0.017	
		95% CI	-0.032, -0.00	
		p-value	0.0299	
		Interaction p-value	0.9892	

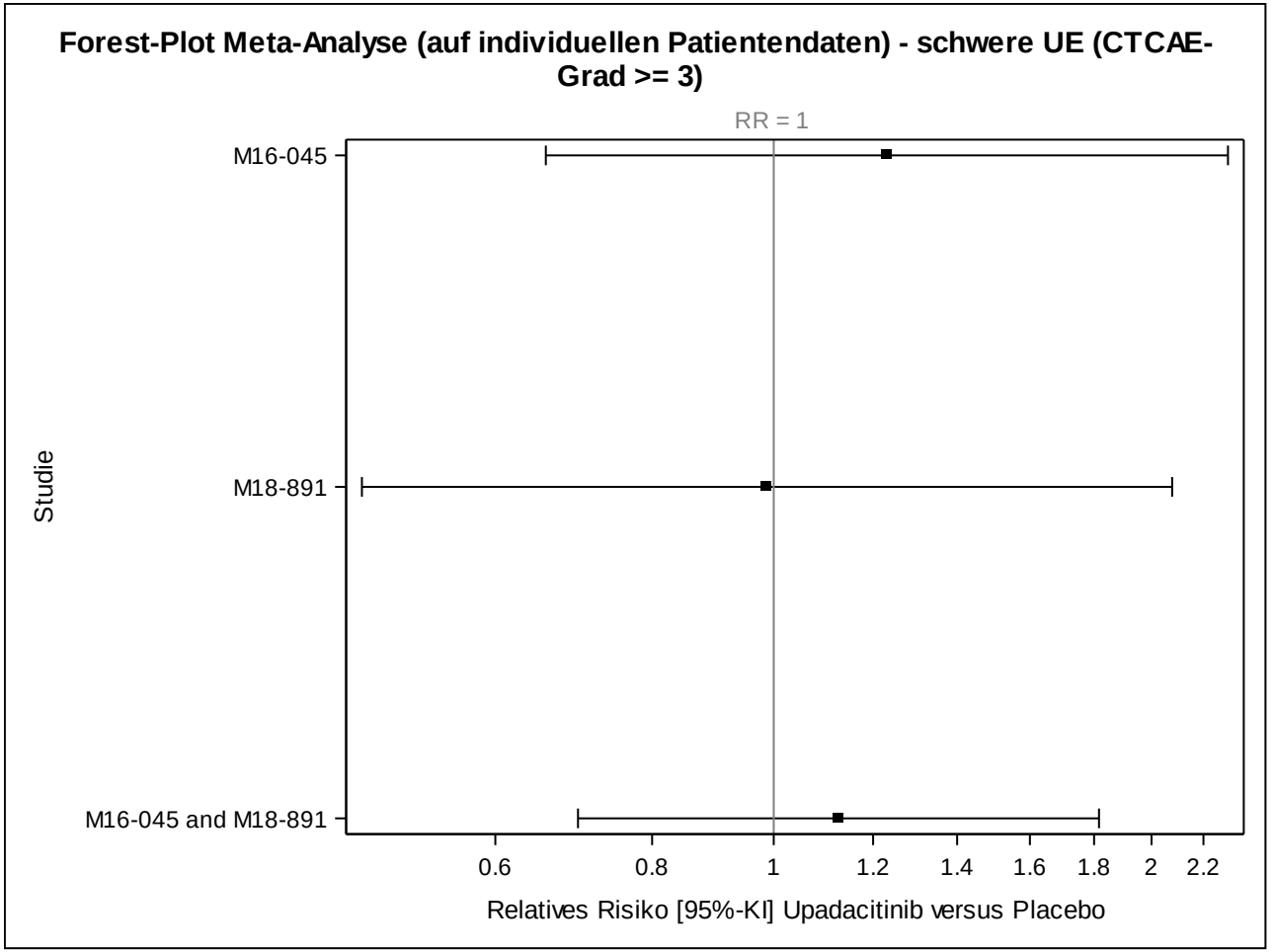
Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
p-Value for interaction from a generalized linear model with treatment, study and treatment by study interaction as covariates with log-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.



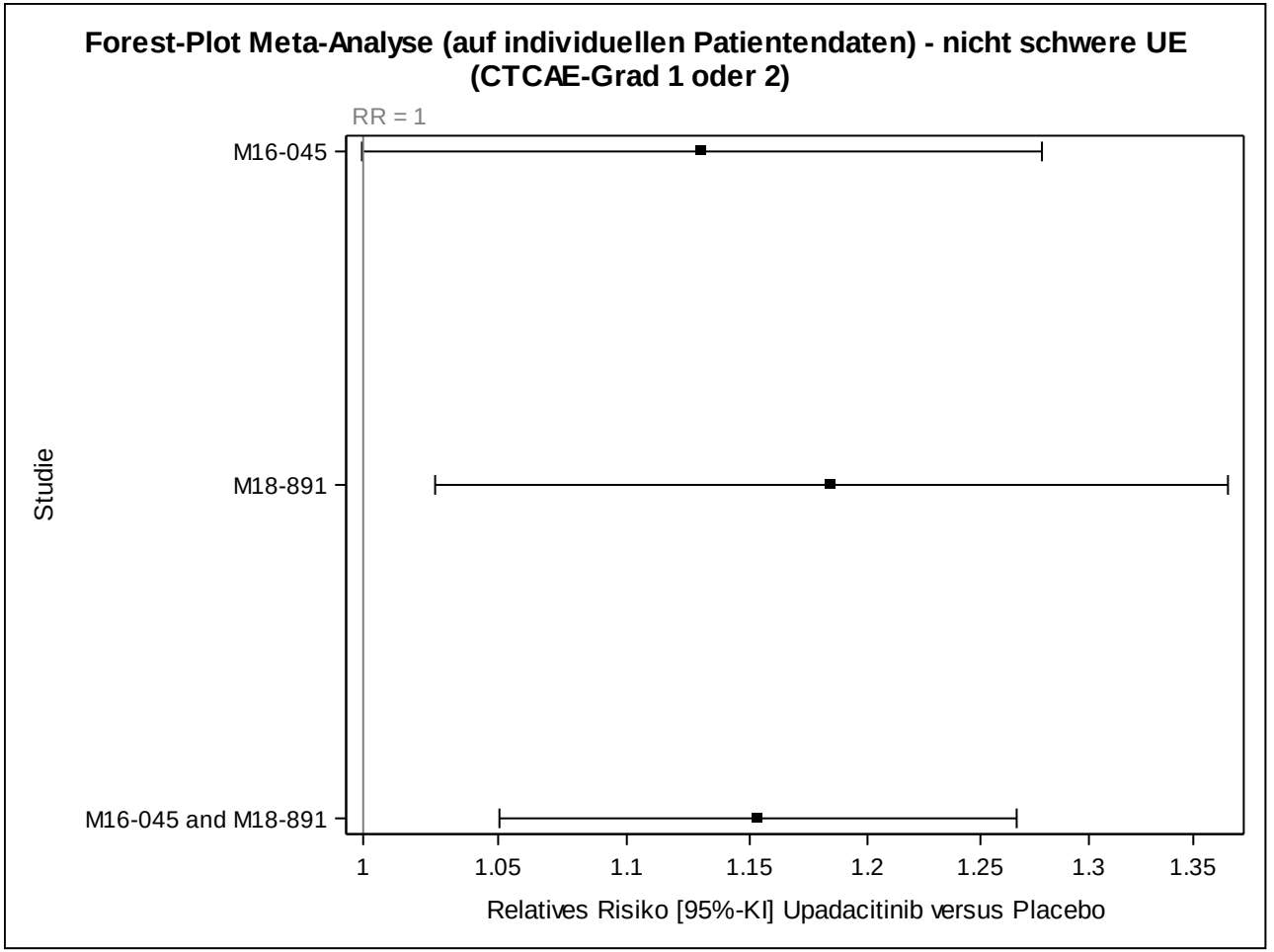
Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.



Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

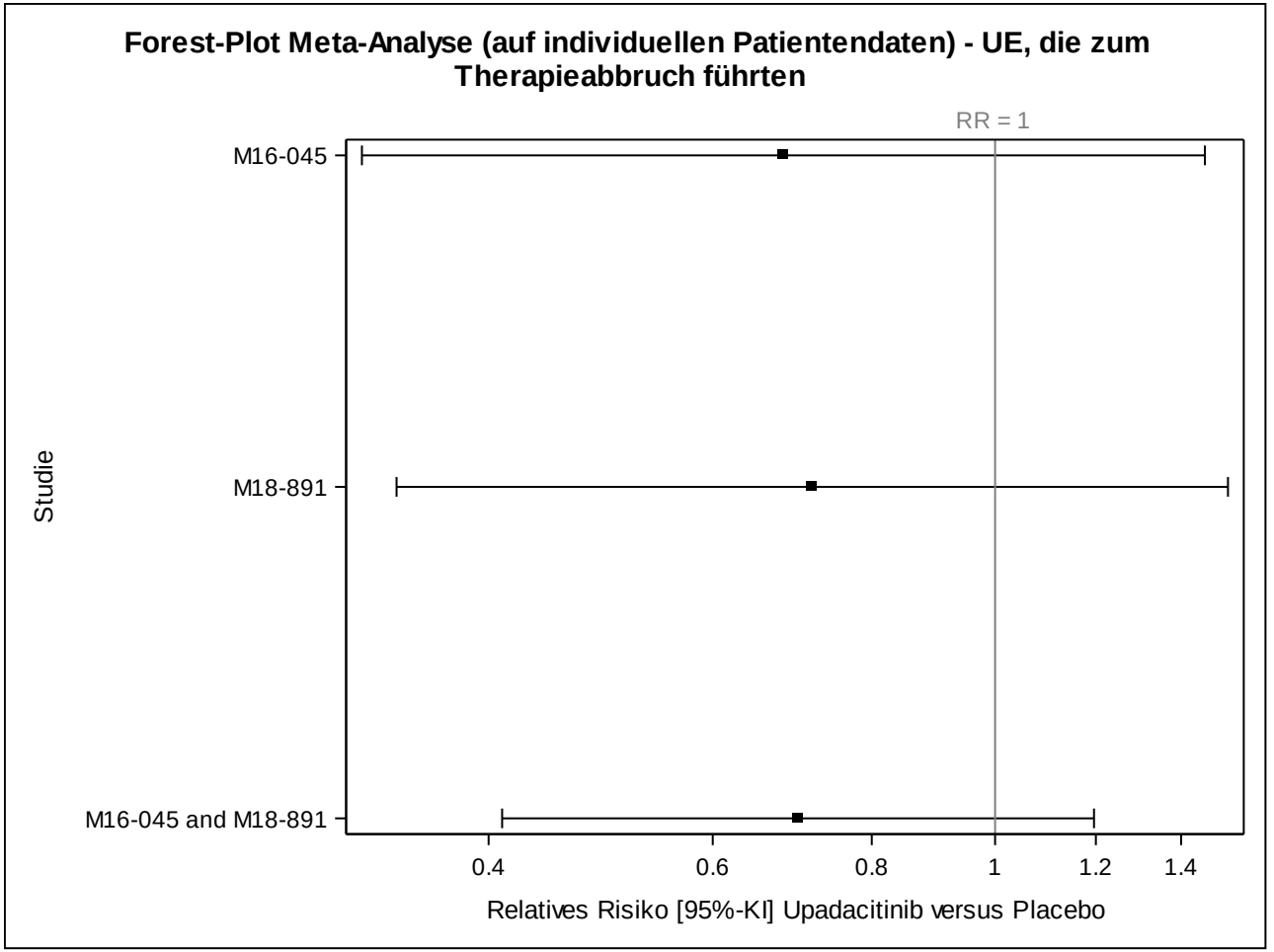


Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

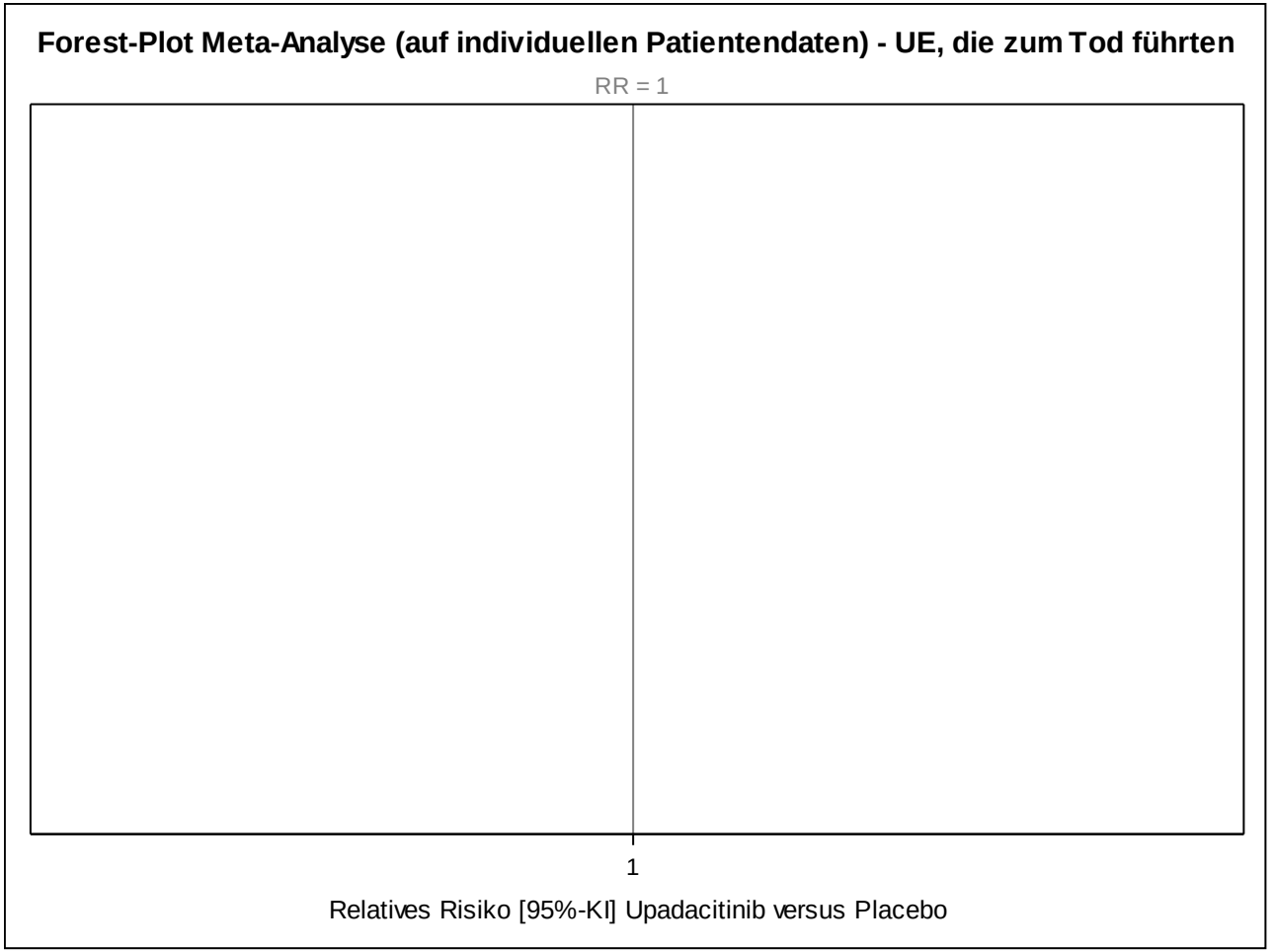


Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Figure 3.4.5.1
Forest Plot - Adverse Events leading to discontinuation of study drug
(ITT_M Population)



Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.



Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Relative Risk, CI and p-value based on a generalized linear model with treatment and study as covariates and logit-/log-/identity-link.
The Upadacitinib arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

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Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.1
Demographic and Baseline Characteristics
(ITT_M Population)

		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)	Total (N=79)
Age (years)	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	15.72 (1.34)	15.10 (1.85)	15.41 (1.64)
	Median	16.00	15.00	16.00
	Q1, Q3	15.00, 17.00	14.00, 16.50	14.00, 17.00
	Min, Max	13.00, 18.00	12.00, 18.00	12.00, 18.00
Sex - n (%)	Female	17 (43.6)	24 (60.0)	41 (51.9)
	Male	22 (56.4)	16 (40.0)	38 (48.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Race - n (%)	White	27 (69.2)	29 (72.5)	56 (70.9)
	Black	4 (10.3)	3 (7.5)	7 (8.9)
	Asian	7 (17.9)	8 (20.0)	15 (19.0)
	Other	1 (2.6)	0 (0.0)	1 (1.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Geographic Region - n (%)	US/PR/Canada	18 (46.2)	18 (45.0)	36 (45.6)
	Other	21 (53.8)	22 (55.0)	43 (54.4)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Weight (kg)	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	63.39 (18.83)	62.48 (18.42)	62.93 (18.51)
	Median	59.00	59.20	59.00
	Q1, Q3	49.00, 71.40	44.45, 73.95	47.00, 73.50
	Min, Max	40.10, 125.50	40.10, 105.40	40.10, 125.50
Weight (kg) - n (%)	< Median (73.11)	30 (76.9)	29 (72.5)	59 (74.7)
	>= Median (73.11)	9 (23.1)	11 (27.5)	20 (25.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Body Mass Index (kg/m^2)	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	23.01 (5.60)	23.35 (5.63)	23.18 (5.58)
	Median	21.60	22.05	21.90
	Q1, Q3	18.90, 25.10	19.15, 26.60	18.90, 25.80
	Min, Max	16.70, 41.50	16.30, 40.00	16.30, 41.50
Body Mass Index (kg/m^2) - n (%)	< 25	29 (74.4)	27 (67.5)	56 (70.9)
	25 - < 30	6 (15.4)	8 (20.0)	14 (17.7)
	>= 30	4 (10.3)	5 (12.5)	9 (11.4)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.1
Demographic and Baseline Characteristics
(ITT_M Population)

		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)	Total (N=79)
Baseline EASI	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	30.02 (11.27)	31.52 (13.74)	30.78 (12.53)
	Median	29.80	27.85	28.60
	Q1, Q3	21.80, 34.90	18.80, 41.95	19.10, 37.50
	Min, Max	16.10, 59.50	16.00, 59.60	16.00, 59.60
Baseline EASI - n (%)	< Median (25.8)	15 (38.5)	16 (40.0)	31 (39.2)
	>= Median (25.8)	24 (61.5)	24 (60.0)	48 (60.8)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline vIGA-AD	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	3.51 (0.51)	3.55 (0.50)	3.53 (0.50)
	Median	4.00	4.00	4.00
	Q1, Q3	3.00, 4.00	3.00, 4.00	3.00, 4.00
	Min, Max	3.00, 4.00	3.00, 4.00	3.00, 4.00
Baseline vIGA-AD - n (%)	3 (Moderate)	19 (48.7)	18 (45.0)	37 (46.8)
	4 (Severe)	20 (51.3)	22 (55.0)	42 (53.2)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline hsCRP	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	2.07 (3.51)	2.03 (5.11)	2.05 (4.37)
	Median	0.64	0.54	0.61
	Q1, Q3	0.27, 1.89	0.20, 1.43	0.20, 1.52
	Min, Max	0.20, 18.70	0.20, 30.10	0.20, 30.10
Baseline hsCRP - n (%)	< Median (1.41)	27 (69.2)	30 (75.0)	57 (72.2)
	>= Median (1.41)	12 (30.8)	10 (25.0)	22 (27.8)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Topical Therapy - n (%)	With	37 (94.9)	39 (97.5)	76 (96.2)
	Without	2 (5.1)	1 (2.5)	3 (3.8)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Systemic Therapy - n (%)	With	22 (56.4)	18 (45.0)	40 (50.6)
	Without	17 (43.6)	22 (55.0)	39 (49.4)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Phototherapy - n (%)	With	10 (25.6)	9 (22.5)	19 (24.1)
	Without	29 (74.4)	31 (77.5)	60 (75.9)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline BSA	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	43.01 (22.78)	47.81 (25.30)	45.44 (24.05)
	Median	42.00	39.00	40.00
	Q1, Q3	20.00, 63.00	28.50, 72.50	27.00, 67.50
	Min, Max	12.00, 88.00	12.00, 98.00	12.00, 98.00

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)	Total (N=79)
Worst Pruritus NRS (Weekly Average)	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	6.71 (2.02)	7.10 (1.77)	6.91 (1.90)
	Median	6.83	7.14	7.00
	Q1, Q3	5.83, 8.40	6.07, 8.34	6.00, 8.40
	Min, Max	1.00, 9.60	2.00, 10.00	1.00, 10.00
Baseline PGIS	n (missing)	39 (0)	39 (1)	78 (1)
	Mean (SD)	3.97 (1.31)	4.15 (1.41)	4.06 (1.35)
	Median	4.00	4.00	4.00
	Q1, Q3	3.00, 5.00	3.00, 5.00	3.00, 5.00
	Min, Max	0.00, 6.00	1.00, 6.00	0.00, 6.00
Disease duration since diagnosis (years)	n (missing)	39 (0)	39 (1)	78 (1)
	Mean (SD)	11.88 (5.08)	12.82 (3.64)	12.35 (4.42)
	Median	13.53	13.85	13.84
	Q1, Q3	8.26, 15.86	10.81, 15.16	10.64, 15.66
	Min, Max	0.10, 17.92	2.46, 17.20	0.10, 17.92
Any Allergic Comorbidity - n (%)	With	28 (71.8)	32 (80.0)	60 (75.9)
	Without	11 (28.2)	8 (20.0)	19 (24.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Food Allergy - n (%)	With	20 (51.3)	15 (37.5)	35 (44.3)
	Without	19 (48.7)	25 (62.5)	44 (55.7)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Asthma - n (%)	With	18 (46.2)	23 (57.5)	41 (51.9)
	Without	21 (53.8)	17 (42.5)	38 (48.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Allergic Rhinitis - n (%)	With	15 (38.5)	19 (47.5)	34 (43.0)
	Without	24 (61.5)	21 (52.5)	45 (57.0)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Eosinophilic Esophagitis - n (%)	With	0 (0.0)	0 (0.0)	0 (0.0)
	Without	39 (100.0)	40 (100.0)	79 (100.0)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Nasal Polyps - n (%)	With	1 (2.6)	0 (0.0)	1 (1.3)
	Without	38 (97.4)	40 (100.0)	78 (98.7)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.2
Subject Disposition
(ITT_M Population)

Status	Upadacitinib + TCS(N=39) n (%)	Placebo + TCS(N=40) n (%)	Total(N=79) n (%)
Received study drug in DB period	39 (100.0)	39 (97.5)	78 (98.7)
Received first rescue medication in DB period	4 (10.3)	7 (17.5)	11 (13.9)
Received first topical rescue medication in DB period	4 (10.3)	4 (10.0)	8 (10.1)
Plain topical corticosteroid in DB period	4 (10.3)	4 (10.0)	8 (10.1)
High potency topical corticosteroid in DB period	4 (10.3)	4 (10.0)	8 (10.1)
Medium potency topical corticosteroid in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Low potency topical corticosteroid in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Topical calcineurin inhibitor in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Other topical therapy in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Received first systemic rescue medication in DB period	0 (0.0)	3 (7.5)	3 (3.8)
Biologic systemic therapy in DB period	0 (0.0)	1 (2.5)	1 (1.3)
Non-biologic immunomodulating systemic therapy in DB period	0 (0.0)	3 (7.5)	3 (3.8)
Other systemic therapy in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Received first rescue phototherapy in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Completed DB period	38 (97.4)	36 (90.0)	74 (93.7)
Ongoing DB Period	0 (0.0)	1 (2.5)	1 (1.3)
Discontinued study in DB period	1 (2.6)	3 (7.5)	4 (5.1)
Primary reason			
Adverse event	1 (2.6)	0 (0.0)	1 (1.3)
Withdrawal of consent	0 (0.0)	1 (2.5)	1 (1.3)
Lost to follow-up	0 (0.0)	2 (5.0)	2 (2.5)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Completed DB period on study drug	38 (97.4)	36 (90.0)	74 (93.7)
Ongoing DB Period on study drug	0 (0.0)	0 (0.0)	0 (0.0)
Discontinued study drug in DB period	1 (2.6)	3 (7.5)	4 (5.1)
Primary reason			
Adverse event	1 (2.6)	1 (2.5)	2 (2.5)
Withdrawal of consent	0 (0.0)	0 (0.0)	0 (0.0)
Lost to follow-up	0 (0.0)	2 (5.0)	2 (2.5)
Lack of efficacy	0 (0.0)	0 (0.0)	0 (0.0)
EASI score - worsening of 25%	0 (0.0)	0 (0.0)	0 (0.0)
Systemic rescue	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing status, DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, COVID: Corona Virus Disease
One patient may receive more than one rescue therapy (topical, systemic, phototherapy).
If a patient receives systemic rescue therapy the primary reason for discontinuation of study drug does not necessarily have to be systemic rescue.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.2
Subject Disposition
(ITT_M Population)

Status	Upadacitinib + TCS(N=39) n (%)	Placebo + TCS(N=40) n (%)	Total(N=79) n (%)
Entered BE period	38 (97.4)	36 (90.0)	74 (93.7)
Received study drug in BE period	37 (94.9)	36 (90.0)	73 (92.4)
Received first rescue medication in BE period	4 (10.3)	1 (2.5)	5 (6.3)
Received first topical rescue medication in BE period	2 (5.1)	1 (2.5)	3 (3.8)
Plain topical corticosteroid in BE period	2 (5.1)	1 (2.5)	3 (3.8)
High potency topical corticosteroid in BE period	2 (5.1)	1 (2.5)	3 (3.8)
Medium potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Low potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Topical calcineurin inhibitor in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Other topical therapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Received first systemic rescue medication in BE period	2 (5.1)	0 (0.0)	2 (2.5)
Biologic systemic therapy in BE period	1 (2.6)	0 (0.0)	1 (1.3)
Non-biologic immunomodulating systemic therapy in BE period	1 (2.6)	0 (0.0)	1 (1.3)
Other systemic therapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Received first rescue phototherapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Ongoing BE Period	38 (97.4)	33 (82.5)	71 (89.9)
Discontinued Study in BE period	0 (0.0)	3 (7.5)	3 (3.8)
Primary reason			
Adverse event	0 (0.0)	1 (2.5)	1 (1.3)
Withdrawal of consent	0 (0.0)	1 (2.5)	1 (1.3)
Lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	1 (2.5)	1 (1.3)
Ongoing study drug in BE period	34 (87.2)	33 (82.5)	67 (84.8)
Discontinued study drug in BE Period	3 (7.7)	3 (7.5)	6 (7.6)
Primary reason			
Adverse event	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawal of consent	0 (0.0)	1 (2.5)	1 (1.3)
Lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)
Lack of efficacy	2 (5.1)	2 (5.0)	4 (5.1)
EASI score - worsening of 25%	1 (2.6)	0 (0.0)	1 (1.3)
Systemic rescue	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing status, DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, COVID: Corona Virus Disease
One patient may receive more than one rescue therapy (topical, systemic, phototherapy).
If a patient receives systemic rescue therapy the primary reason for discontinuation of study drug does not necessarily have to be systemic rescue.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)	Total (N=79)
Study duration in DB period (Week 0 - 16) (Weeks)	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	15.80 (1.96)	15.89 (3.98)	15.85 (3.13)
	Median	16.00	16.00	16.00
	Q1, Q3	16.00, 16.29	15.86, 16.14	15.86, 16.14
	Min, Max	4.14, 17.14	2.29, 35.43	2.29, 35.43
Treatment duration in DB period (Week 0 - 16) (Weeks)	n (missing)	39 (0)	39 (1)	78 (1)
	Mean (SD)	15.74 (2.00)	15.29 (2.39)	15.51 (2.20)
	Median	16.00	16.00	16.00
	Q1, Q3	16.00, 16.29	15.86, 16.14	15.86, 16.14
	Min, Max	4.00, 17.14	4.29, 16.43	4.00, 17.14
Observation time for safety at Week 16 (Weeks)	n (missing)	39 (0)	39 (1)	78 (1)
	Mean (SD)	16.06 (1.34)	15.75 (1.37)	15.91 (1.36)
	Median	16.14	16.14	16.14
	Q1, Q3	16.14, 16.43	16.00, 16.29	16.00, 16.29
	Min, Max	8.29, 17.29	8.57, 16.57	8.29, 17.29
Body Surface Area (BSA): Observation time at Week 16 (Weeks)	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	15.93 (1.98)	14.28 (4.40)	15.09 (3.50)
	Median	16.14	16.14	16.14
	Q1, Q3	16.14, 16.43	15.86, 16.14	16.00, 16.29
	Min, Max	4.14, 17.29	0.14, 16.57	0.14, 17.29
Eczema Area and Severity Index (EASI): Observation time at Week 16 (Weeks)	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	15.93 (1.98)	14.28 (4.40)	15.09 (3.50)
	Median	16.14	16.14	16.14
	Q1, Q3	16.14, 16.43	15.86, 16.14	16.00, 16.29
	Min, Max	4.14, 17.29	0.14, 16.57	0.14, 17.29
Patient Global Impression of Severity (PGIS): Observation time at Week 16 (Weeks)	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	15.93 (1.98)	13.98 (4.58)	14.94 (3.66)
	Median	16.14	16.14	16.14
	Q1, Q3	16.14, 16.43	15.57, 16.14	16.00, 16.29
	Min, Max	4.14, 17.29	0.14, 16.57	0.14, 17.29
Worst Pruritus NRS: Observation time at Week 16 (Weeks)	n (missing)	39 (0)	40 (0)	79 (0)
	Mean (SD)	15.67 (1.94)	14.06 (4.16)	14.86 (3.34)
	Median	16.14	16.00	16.14
	Q1, Q3	16.00, 16.14	15.14, 16.14	15.86, 16.14
	Min, Max	4.14, 16.14	1.14, 16.14	1.14, 16.14

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, NRS: Numeric Rating Scale
Study duration is calculated as (date of first dose of study drug - minimum(date of first dose of study drug in BE period, date of end of study) + 1) divided by 7
Treatment duration is calculated as (date of first dose of study drug - date of last dose of study drug in DB period + 1) divided by 7
Observation time for Safety is calculated as (date of first dose of study drug - minimum(date of first dose of study drug in BE period, date of last dose of study drug in DB period + 30) + 1) divided by 7
Observation time for endpoints is calculated as (date of first dose of study drug - date of last non-missing evaluation in DB period + 1) divided by 7. Evaluations after start of systemic rescue or phototherapy are excluded.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.4
Overview Completion Rates
(ITT_M Population)

Endpoint	Visit	Upadacitinib + TCS(N=39) n (%)	Placebo + TCS(N=40) n (%)
Worst Pruritus Numeric Rating Scale	Baseline	39 (100.0)	40 (100.0)
	Week 1	38 (97.4)	37 (92.5)
	Week 2	37 (94.9)	37 (92.5)
	Week 3	38 (97.4)	37 (92.5)
	Week 4	39 (100.0)	37 (92.5)
	Week 5	38 (97.4)	37 (92.5)
	Week 6	38 (97.4)	37 (92.5)
	Week 7	37 (94.9)	34 (85.0)
	Week 8	37 (94.9)	35 (87.5)
	Week 9	38 (97.4)	35 (87.5)
	Week 10	38 (97.4)	34 (85.0)
	Week 11	37 (94.9)	35 (87.5)
	Week 12	36 (92.3)	36 (90.0)
	Week 13	37 (94.9)	35 (87.5)
	Week 14	37 (94.9)	33 (82.5)
	Week 15	35 (89.7)	33 (82.5)
	Week 16	35 (89.7)	30 (75.0)
Patient Global Impression of Severity (PGIS)	Baseline	39 (100.0)	39 (97.5)
	Week 2	37 (94.9)	38 (95.0)
	Week 4	38 (97.4)	38 (95.0)
	Week 12	38 (97.4)	37 (92.5)
	Week 16	38 (97.4)	35 (87.5)

N: Number of subjects, n: Number of subjects with non missing values
All observed data will be used in the analysis.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 1.5
Overview Missings and Rescue Therapy at Week 16
(ITT_M Population)

		Upadacitinib + TCS(N=39)							Placebo + TCS(N=40)						
		missings			rescue therapy				missings			rescue therapy			
Endpoint	Visit	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)
EASI	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 4	1 (2.6)	1 (2.6)	0 (0.0)	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 8	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	4 (10.0)	4 (10.0)	0 (0.0)	5 (12.5)	3 (7.5)	2 (5.0)	0 (0.0)
	Week 12	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 16	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
Pruritus	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	2 (5.1)	2 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 3	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 5	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	2 (5.0)	2 (5.0)	0 (0.0)	0 (0.0)
	Week 6	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	3 (7.5)	2 (5.0)	1 (2.5)	0 (0.0)
	Week 7	2 (5.1)	2 (5.1)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	6 (15.0)	6 (15.0)	0 (0.0)	5 (12.5)	3 (7.5)	2 (5.0)	0 (0.0)
	Week 8	2 (5.1)	2 (5.1)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	5 (12.5)	5 (12.5)	0 (0.0)	5 (12.5)	3 (7.5)	2 (5.0)	0 (0.0)
	Week 9	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	5 (12.5)	5 (12.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 10	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	6 (15.0)	6 (15.0)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 11	2 (5.1)	2 (5.1)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	5 (12.5)	5 (12.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 12	3 (7.7)	3 (7.7)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	4 (10.0)	4 (10.0)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 13	2 (5.1)	2 (5.1)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	5 (12.5)	5 (12.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 14	2 (5.1)	2 (5.1)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	7 (17.5)	7 (17.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 15	4 (10.3)	4 (10.3)	0 (0.0)	2 (5.1)	2 (5.1)	0 (0.0)	0 (0.0)	7 (17.5)	7 (17.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 16	4 (10.3)	4 (10.3)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	10 (25.0)	10 (25.0)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
BSA	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 4	1 (2.6)	1 (2.6)	0 (0.0)	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 8	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	5 (12.5)	3 (7.5)	2 (5.0)	0 (0.0)
	Week 12	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 16	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
PGIS	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	2 (5.1)	2 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 4	1 (2.6)	1 (2.6)	0 (0.0)	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 12	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
	Week 16	1 (2.6)	1 (2.6)	0 (0.0)	3 (7.7)	3 (7.7)	0 (0.0)	0 (0.0)	5 (12.5)	5 (12.5)	0 (0.0)	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)

N: Number of subjects, EASI: Eczema Area and Severity Index, BSA: Body Surface Area, PGIS: Patient Global Impression of Severity
COVID summarizes the number of subjects with missing data due to COVID-19 infection or logistical restriction, No-COVID summarizes all other subjects with missing data.
topical summarizes the number of rescued subjects of the following categories: plain topical corticosteroids, high/medium/low potency topical corticosteroids, topical calcineurin inhibitor, other topical therapy
systemic summarizes the number of rescued subjects of the following categories: biologic systemic therapy, non-biologic immunomodulating systemic therapy, other systemic therapy
photo summarizes the number of rescued subjects with phototherapy.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)

Table 2.1.1

Descriptive Statistics for Mean Values and Change from Baseline - Eczema Area and Severity Index (EASI)

(ITT_M Population)

	Upadacitinib + TCS(N=39)				Placebo + TCS(N=40)			
	Value at Visit			Change from Baseline	Value at Visit			Change from Baseline
Visit	n	n_miss (%)	Mean (SD)	n Mean (SD)	n	n_miss (%)	Mean (SD)	n Mean (SD)
Baseline	39	0 (0.0)	30.02 (11.27)		40	0 (0.0)	31.52 (13.74)	
Week 2	38	1 (2.6)	14.73 (13.50)	38 -15.65 (11.01)	39	1 (2.5)	24.09 (17.09)	39 -7.35 (9.35)
Week 4	38	1 (2.6)	10.17 (10.13)	38 -20.16 (10.51)	38	2 (5.0)	20.83 (17.82)	38 -10.98 (12.82)
Week 8	38	1 (2.6)	8.47 (11.16)	38 -21.71 (11.40)	34	6 (15.0)	15.21 (13.09)	34 -14.23 (12.89)
Week 12	38	1 (2.6)	7.25 (9.01)	38 -22.93 (13.01)	34	6 (15.0)	15.08 (14.49)	34 -14.95 (10.70)
Week 16	38	1 (2.6)	7.89 (10.01)	38 -22.29 (13.43)	34	6 (15.0)	14.66 (14.99)	34 -15.37 (13.09)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.1.2
Descriptive Statistics for Mean Values and Change from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT_M Population)

	Upadacitinib + TCS(N=39)					Placebo + TCS(N=40)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	39	0 (0.0)	6.71 (2.02)			40	0 (0.0)	7.10 (1.77)		
Week 1	38	1 (2.6)	5.04 (2.18)	38	-1.68 (1.80)	37	3 (7.5)	6.30 (1.87)	37	-0.90 (1.79)
Week 2	37	2 (5.1)	4.29 (2.25)	37	-2.59 (2.26)	37	3 (7.5)	5.86 (2.04)	37	-1.15 (2.09)
Week 3	38	1 (2.6)	3.72 (2.41)	38	-3.05 (2.27)	37	3 (7.5)	5.48 (2.25)	37	-1.58 (2.08)
Week 4	39	0 (0.0)	3.48 (2.38)	39	-3.23 (2.33)	37	3 (7.5)	5.30 (2.17)	37	-1.76 (2.29)
Week 5	38	1 (2.6)	3.48 (2.34)	38	-3.37 (2.25)	37	3 (7.5)	5.42 (2.30)	37	-1.63 (2.43)
Week 6	38	1 (2.6)	3.49 (2.44)	38	-3.36 (2.31)	36	4 (10.0)	5.13 (2.31)	36	-1.93 (2.52)
Week 7	37	2 (5.1)	3.34 (2.60)	37	-3.53 (2.56)	32	8 (20.0)	4.84 (2.08)	32	-1.99 (2.67)
Week 8	37	2 (5.1)	3.29 (2.30)	37	-3.53 (2.40)	33	7 (17.5)	4.92 (2.00)	33	-2.10 (2.47)
Week 9	38	1 (2.6)	3.13 (2.10)	38	-3.72 (2.28)	32	8 (20.0)	4.94 (2.07)	32	-2.00 (2.33)
Week 10	38	1 (2.6)	3.07 (2.02)	38	-3.78 (2.23)	31	9 (22.5)	4.91 (2.08)	31	-2.01 (2.31)
Week 11	37	2 (5.1)	3.20 (2.10)	37	-3.75 (2.56)	32	8 (20.0)	4.93 (2.26)	32	-2.01 (2.25)
Week 12	36	3 (7.7)	3.11 (2.07)	36	-3.79 (2.48)	33	7 (17.5)	4.96 (2.26)	33	-2.07 (2.22)
Week 13	37	2 (5.1)	2.86 (2.07)	37	-3.93 (2.29)	32	8 (20.0)	5.05 (2.41)	32	-1.93 (2.30)
Week 14	37	2 (5.1)	2.91 (2.03)	37	-4.02 (2.22)	30	10 (25.0)	5.02 (2.45)	30	-1.91 (2.32)
Week 15	35	4 (10.3)	3.04 (2.07)	35	-3.83 (2.26)	30	10 (25.0)	4.89 (2.47)	30	-2.09 (2.22)
Week 16	35	4 (10.3)	2.98 (2.10)	35	-3.73 (2.36)	27	13 (32.5)	5.00 (2.59)	27	-2.04 (2.28)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.1.3
Descriptive Statistics for Mean Values and Change from Baseline - Body Surface Area (BSA)
(ITT_M Population)

	Upadacitinib + TCS(N=39)				Placebo + TCS(N=40)			
	Value at Visit			Change from Baseline	Value at Visit			Change from Baseline
Visit	n	n_miss (%)	Mean (SD)	n Mean (SD)	n	n_miss (%)	Mean (SD)	n Mean (SD)
Baseline	39	0 (0.0)	43.01 (22.78)		40	0 (0.0)	47.81 (25.30)	
Week 2	38	1 (2.6)	24.65 (21.71)	38 -19.10 (21.76)	38	2 (5.0)	40.29 (28.86)	38 -8.06 (12.85)
Week 4	38	1 (2.6)	18.97 (19.93)	38 -24.86 (24.60)	38	2 (5.0)	37.90 (29.61)	38 -10.50 (19.39)
Week 8	38	1 (2.6)	16.96 (18.43)	38 -26.36 (23.08)	35	5 (12.5)	31.63 (25.40)	35 -12.90 (18.61)
Week 12	38	1 (2.6)	16.59 (21.51)	38 -26.74 (23.74)	34	6 (15.0)	29.50 (26.20)	34 -14.16 (19.88)
Week 16	38	1 (2.6)	17.22 (22.55)	38 -26.10 (25.75)	34	6 (15.0)	27.76 (25.58)	34 -15.89 (21.60)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.1.4
Descriptive Statistics for Mean Values and Change from Baseline - Patient Global Impression of Severity (PGIS)
(ITT_M Population)

	Upadacitinib + TCS(N=39)				Placebo + TCS(N=40)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	n	n_miss (%) Mean (SD)	n	Mean (SD)	n	n_miss (%) Mean (SD)	n	Mean (SD)
Baseline	39	0 (0.0) 3.97 (1.31)			39	1 (2.5) 4.15 (1.41)		
Week 2	37	2 (5.1) 1.78 (1.16)	37	-2.24 (1.46)	38	2 (5.0) 3.29 (1.58)	37	-0.70 (1.53)
Week 4	38	1 (2.6) 1.84 (1.17)	38	-2.13 (1.44)	38	2 (5.0) 3.00 (1.43)	37	-1.05 (1.20)
Week 12	38	1 (2.6) 1.74 (1.22)	38	-2.24 (1.68)	34	6 (15.0) 2.88 (1.37)	33	-1.15 (1.39)
Week 16	38	1 (2.6) 1.82 (1.37)	38	-2.16 (1.53)	32	8 (20.0) 2.94 (1.48)	31	-1.10 (1.42)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.2.1
Mixed Effects Model with Repeated Measure for Changes from Baseline - Eczema Area and Severity Index (EASI)
(ITT_M Population)

	Upadacitinib + TCS(N=39)			Placebo + TCS(N=40)			Difference of LSMeans (95% CI)			p-Value	Hedges` g (95% CI)		p-Value
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)							
Week 2			-15.65 (1.69)			-7.11 (1.68)	-8.54 (	-13.29,	-3.80)				
Week 4			-19.96 (1.81)			-10.49 (1.82)	-9.47 (	-14.58,	-4.37)				
Week 8			-21.41 (1.82)			-12.85 (1.87)	-8.56 (	-13.77,	-3.34)				
Week 12			-22.68 (1.78)			-13.83 (1.83)	-8.85 (	-13.94,	-3.76)				
Week 16			-22.08 (1.97)			-14.42 (2.05)	-7.66 (	-13.34,	-1.99)				
Overall up to Week 16	39	0	-20.36 (1.54)	39	1	-11.74 (1.56)	-8.62 (	-13.00,	-4.24)	0.0002	-0.88 (-1.35,	-0.41)	0.0002

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.2.2
Mixed Effects Model with Repeated Measure for Changes from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT_M Population)

Visit	Upadacitinib + TCS(N=39) N*	N**	LSMean (SE)	Placebo + TCS(N=40) N*	N**	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges` g (95% CI)	p-Value
Week 1			-1.71 (0.27)			-0.82 (0.27)	-0.89 (-1.66, -0.12)			
Week 2			-2.63 (0.32)			-1.10 (0.32)	-1.54 (-2.44, -0.64)			
Week 3			-3.11 (0.33)			-1.47 (0.33)	-1.64 (-2.58, -0.70)			
Week 4			-3.32 (0.34)			-1.66 (0.34)	-1.67 (-2.63, -0.71)			
Week 5			-3.38 (0.35)			-1.53 (0.35)	-1.85 (-2.83, -0.86)			
Week 6			-3.36 (0.36)			-1.76 (0.37)	-1.60 (-2.63, -0.58)			
Week 7			-3.51 (0.38)			-1.92 (0.38)	-1.60 (-2.67, -0.52)			
Week 8			-3.58 (0.35)			-1.84 (0.36)	-1.74 (-2.74, -0.74)			
Week 9			-3.72 (0.33)			-1.86 (0.34)	-1.86 (-2.81, -0.90)			
Week 10			-3.77 (0.34)			-2.04 (0.35)	-1.73 (-2.69, -0.77)			
Week 11			-3.72 (0.35)			-1.88 (0.36)	-1.84 (-2.85, -0.84)			
Week 12			-3.77 (0.34)			-1.90 (0.35)	-1.88 (-2.86, -0.90)			
Week 13			-3.94 (0.34)			-1.86 (0.36)	-2.08 (-3.07, -1.10)			
Week 14			-3.95 (0.34)			-1.76 (0.36)	-2.19 (-3.18, -1.20)			
Week 15			-3.84 (0.34)			-1.89 (0.36)	-1.95 (-2.94, -0.95)			
Week 16			-3.85 (0.37)			-1.97 (0.39)	-1.89 (-2.95, -0.82)			
Overall up to Week 16	39	0	-3.45 (0.29)	40	0	-1.70 (0.29)	-1.75 (-2.57, -0.92)	<.0001	-0.94 (-1.41, -0.48)	<.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.2.3
Mixed Effects Model with Repeated Measure for Changes from Baseline - Body Surface Area (BSA)
(ITT_M Population)

	Upadacitinib + TCS(N=39)			Placebo + TCS(N=40)			Difference of LSMeans (95% CI)				Hedges` g (95% CI)	
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)				p-Value		p-Value
Week 2			-19.50 (2.91)			-5.93 (2.91)	-13.57 (	-21.79,	-5.35)			
Week 4			-25.03 (3.24)			-8.98 (3.25)	-16.05 (	-25.19,	-6.91)			
Week 8			-26.54 (2.95)			-10.94 (2.99)	-15.59 (	-23.97,	-7.21)			
Week 12			-26.92 (3.22)			-12.94 (3.30)	-13.98 (	-23.17,	-4.80)			
Week 16			-26.43 (3.42)			-14.98 (3.57)	-11.45 (	-21.31,	-1.58)			
Overall up to Week 16	39	0	-24.88 (2.72)	39	1	-10.76 (2.75)	-14.13 (	-21.83,	-6.42)	0.0005	-0.82 (-1.28, -0.36)	0.0005

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.2.4
Mixed Effects Model with Repeated Measure for Changes from Baseline - Patient Global Impression of Severity (PGIS)
(ITT_M Population)

	Upadacitinib + TCS(N=39)			Placebo + TCS(N=40)			Difference of LSMeans (95% CI)						
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)				p-Value	Hedges` g (95% CI)		p-Value
Week 2			-2.26 (0.20)			-0.72 (0.20)	-1.54 (	-2.12,	-0.97)				
Week 4			-2.19 (0.18)			-1.04 (0.18)	-1.15 (	-1.66,	-0.64)				
Week 12			-2.29 (0.20)			-1.09 (0.21)	-1.20 (	-1.77,	-0.63)				
Week 16			-2.21 (0.20)			-1.00 (0.22)	-1.21 (	-1.80,	-0.61)				
Overall up to Week 16	39	0	-2.24 (0.15)	38	2	-0.96 (0.15)	-1.28 (	-1.70,	-0.85)	<.0001	-1.34 (-1.83,	-0.84)	<.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.1
Eczema Area and Severity Index (EASI) 75 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	13 (33.3)	5 (12.5)
	Number of imputations (NRI), n (%)	1 (2.6)	1 (2.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	20 (51.3)	12 (30.0)
	Number of imputations (NRI), n (%)	1 (2.6)	2 (5.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	22 (56.4)	8 (20.0)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	25 (64.1)	14 (35.0)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	23 (59.0)	13 (32.5)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	2.971	
	95% CI	1.184, 7.458	
	p-value	0.0204	
	Relative Risk	1.810	
	95% CI	1.070, 3.061	
	p-value	0.0270	
	Risk Difference	0.264	
	95% CI	0.053, 0.476	
	p-value	0.0143	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.2
Eczema Area and Severity Index (EASI) 90 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	4 (10.3)	1 (2.5)
	Number of imputations (NRI), n (%)	1 (2.6)	1 (2.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	11 (28.2)	5 (12.5)
	Number of imputations (NRI), n (%)	1 (2.6)	2 (5.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	13 (33.3)	5 (12.5)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	15 (38.5)	5 (12.5)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	17 (43.6)	8 (20.0)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	3.088	
	95% CI	1.135, 8.401	
	p-value	0.0273	
	Relative Risk	2.179	
	95% CI	1.065, 4.461	
	p-value	0.0330	
	Risk Difference	0.236	
	95% CI	0.037, 0.435	
	p-value	0.0202	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.3
Eczema Area and Severity Index (EASI) 100 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	1 (2.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	2 (5.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	2 (5.1)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	4 (10.3)	1 (2.5)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	4.393	
	95% CI	0.458, 42.129	
	p-value	0.1994	
	Relative Risk	3.852	
	95% CI	0.458, 32.390	
	p-value	0.2144	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 1	Number of subjects with Response, n (%)	4 (10.3)	3 (7.5)
	Number of imputations (NRI), n (%)	1 (2.6)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	7 (17.9)	4 (10.0)
	Number of imputations (NRI), n (%)	2 (5.1)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 3	Number of subjects with Response, n (%)	14 (35.9)	6 (15.0)
	Number of imputations (NRI), n (%)	1 (2.6)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	16 (41.0)	7 (17.5)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 5	Number of subjects with Response, n (%)	15 (38.5)	8 (20.0)
	Number of imputations (NRI), n (%)	1 (2.6)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 6	Number of subjects with Response, n (%)	16 (41.0)	8 (20.0)
	Number of imputations (NRI), n (%)	1 (2.6)	4 (10.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 7	Number of subjects with Response, n (%)	18 (46.2)	6 (15.0)
	Number of imputations (NRI), n (%)	2 (5.1)	8 (20.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	15 (38.5)	7 (17.5)
	Number of imputations (NRI), n (%)	2 (5.1)	7 (17.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 9	Number of subjects with Response, n (%)	16 (41.0)	5 (12.5)
	Number of imputations (NRI), n (%)	1 (2.6)	8 (20.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 10	Number of subjects with Response, n (%)	17 (43.6)	6 (15.0)
	Number of imputations (NRI), n (%)	1 (2.6)	9 (22.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 11	Number of subjects with Response, n (%)	19 (48.7)	6 (15.0)
	Number of imputations (NRI), n (%)	2 (5.1)	8 (20.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	19 (48.7)	6 (15.0)
	Number of imputations (NRI), n (%)	3 (7.7)	7 (17.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 13	Number of subjects with Response, n (%)	19 (48.7)	5 (12.5)
	Number of imputations (NRI), n (%)	2 (5.1)	8 (20.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 14	Number of subjects with Response, n (%)	22 (56.4)	7 (17.5)
	Number of imputations (NRI), n (%)	2 (5.1)	10 (25.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 15	Number of subjects with Response, n (%)	18 (46.2)	8 (20.0)
	Number of imputations (NRI), n (%)	4 (10.3)	10 (25.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	17 (43.6)	6 (15.0)
	Number of imputations (NRI), n (%)	4 (10.3)	13 (32.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	4.378	
	95% CI	1.494, 12.825	
	p-value	0.0071	
	Relative Risk	2.931	
	95% CI	1.291, 6.653	
	p-value	0.0102	
	Risk Difference	0.301	
	95% CI	0.110, 0.492	
	p-value	0.0021	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 1	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (5.1)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 3	Number of subjects with Response, n (%)	3 (7.7)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	3 (7.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 5	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	3 (7.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 6	Number of subjects with Response, n (%)	3 (7.7)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	4 (10.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 7	Number of subjects with Response, n (%)	2 (5.1)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (5.1)	8 (20.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	2 (5.1)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (5.1)	7 (17.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 9	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	8 (20.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 10	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	9 (22.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 11	Number of subjects with Response, n (%)	1 (2.6)	1 (2.5)
	Number of imputations (NRI), n (%)	2 (5.1)	8 (20.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	3 (7.7)	7 (17.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 13	Number of subjects with Response, n (%)	3 (7.7)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (5.1)	8 (20.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 14	Number of subjects with Response, n (%)	2 (5.1)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (5.1)	10 (25.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 15	Number of subjects with Response, n (%)	2 (5.1)	0 (0.0)
	Number of imputations (NRI), n (%)	4 (10.3)	10 (25.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	3 (7.7)	0 (0.0)
	Number of imputations (NRI), n (%)	4 (10.3)	13 (32.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.6
Body Surface Area (BSA) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	2 (5.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	2 (5.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	2 (5.1)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	5 (12.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	3 (7.7)	1 (2.5)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	3.187	
	95% CI	0.300, 33.890	
	p-value	0.3365	
	Relative Risk	2.842	
	95% CI	0.325, 24.877	
	p-value	0.3453	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.3.7
Patient Global Impression of Severity (PGIS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	2 (5.1)	0 (0.0)
	Number of imputations (NRI), n (%)	2 (5.1)	2 (5.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	4 (10.3)	1 (2.5)
	Number of imputations (NRI), n (%)	1 (2.6)	2 (5.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	4 (10.3)	0 (0.0)
	Number of imputations (NRI), n (%)	1 (2.6)	6 (15.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	7 (17.9)	1 (2.5)
	Number of imputations (NRI), n (%)	1 (2.6)	8 (20.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	8.666	
	95% CI	0.992, 75.705	
	p-value	0.0508	
	Relative Risk	6.793	
	95% CI	0.886, 52.069	
	p-value	0.0652	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.1
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 75 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	13 (34.4)	5 (12.6)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	1 (2.5)
Week 4	Number of subjects with Response, n (%)	20 (51.5)	12 (30.3)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	2 (5.0)
Week 8	Number of subjects with Response, n (%)	22 (56.5)	8 (20.1)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (5.0)
	Number of imputations (MI), n (%)	1 (2.6)	4 (10.0)
Week 12	Number of subjects with Response, n (%)	25 (64.4)	14 (35.4)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 16	Number of subjects with Response, n (%)	23 (59.6)	13 (32.9)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
	Adjusted Analysis		
	Odds Ratio	2.990	
	95% CI	1.183, 7.562	
	p-value	0.0207	
	Relative Risk	1.798	
	95% CI	1.064, 3.040	
	p-value	0.0284	
	Risk Difference	0.266	
	95% CI	0.053, 0.479	
	p-value	0.0144	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.2
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 90 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	4 (10.8)	1 (2.5)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	1 (2.5)
Week 4	Number of subjects with Response, n (%)	11 (28.3)	5 (12.6)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	2 (5.0)
Week 8	Number of subjects with Response, n (%)	13 (33.3)	5 (12.5)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (5.0)
	Number of imputations (MI), n (%)	1 (2.6)	4 (10.0)
Week 12	Number of subjects with Response, n (%)	15 (38.5)	5 (12.6)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 16	Number of subjects with Response, n (%)	17 (43.7)	8 (20.2)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
	Adjusted Analysis		
	Odds Ratio	3.067	
	95% CI	1.125, 8.362	
	p-value	0.0285	
	Relative Risk	2.166	
	95% CI	1.058, 4.434	
	p-value	0.0345	
	Risk Difference	0.235	
	95% CI	0.035, 0.435	
	p-value	0.0211	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.3
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 100 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	1 (2.5)
Week 4	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	2 (5.0)
Week 8	Number of subjects with Response, n (%)	2 (5.1)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (5.0)
	Number of imputations (MI), n (%)	1 (2.6)	4 (10.0)
Week 12	Number of subjects with Response, n (%)	1 (2.6)	0 (0.1)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 16	Number of subjects with Response, n (%)	4 (10.3)	1 (2.5)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
	Adjusted Analysis		
	Odds Ratio	4.393	
	95% CI	0.458, 42.129	
	p-value	0.1994	
	Relative Risk	3.852	
	95% CI	0.458, 32.390	
	p-value	0.2144	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 1	Number of subjects with Response, n (%)	4 (10.3)	3 (7.8)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 2	Number of subjects with Response, n (%)	7 (17.9)	4 (10.4)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	2 (5.1)	3 (7.5)
Week 3	Number of subjects with Response, n (%)	14 (35.9)	6 (15.6)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 4	Number of subjects with Response, n (%)	16 (41.0)	7 (18.7)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	0 (0.0)	3 (7.5)
Week 5	Number of subjects with Response, n (%)	15 (38.5)	9 (21.3)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 6	Number of subjects with Response, n (%)	16 (41.0)	9 (21.3)
	Number of imputations (NRI), n (%)	0 (0.0)	1 (2.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 7	Number of subjects with Response, n (%)	18 (46.6)	7 (18.6)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (5.0)
	Number of imputations (MI), n (%)	2 (5.1)	6 (15.0)
Week 8	Number of subjects with Response, n (%)	15 (38.5)	8 (20.8)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (5.0)
	Number of imputations (MI), n (%)	2 (5.1)	5 (12.5)
Week 9	Number of subjects with Response, n (%)	16 (41.0)	6 (16.0)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	5 (12.5)
Week 10	Number of subjects with Response, n (%)	17 (43.6)	8 (20.0)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	6 (15.0)
Week 11	Number of subjects with Response, n (%)	19 (48.7)	8 (18.8)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	2 (5.1)	5 (12.5)
Week 12	Number of subjects with Response, n (%)	20 (50.4)	7 (17.5)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	3 (7.7)	4 (10.0)
Week 13	Number of subjects with Response, n (%)	19 (49.9)	7 (16.8)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	2 (5.1)	5 (12.5)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 14	Number of subjects with Response, n (%)	22 (56.4)	9 (21.6)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	2 (5.1)	7 (17.5)
Week 15	Number of subjects with Response, n (%)	18 (47.3)	10 (24.3)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	4 (10.3)	7 (17.5)
Week 16	Number of subjects with Response, n (%)	20 (50.0)	8 (20.8)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	4 (10.3)	10 (25.0)
	Adjusted Analysis		
	Odds Ratio	3.800	
	95% CI	1.373, 10.519	
	p-value	0.0102	
	Relative Risk	2.440	
	95% CI	1.207, 4.932	
	p-value	0.0130	
	Risk Difference	0.294	
	95% CI	0.085, 0.503	
	p-value	0.0059	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 1	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	2 (5.1)	3 (7.5)
Week 3	Number of subjects with Response, n (%)	3 (7.7)	0 (0.1)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 4	Number of subjects with Response, n (%)	3 (7.7)	0 (0.1)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	0 (0.0)	3 (7.5)
Week 5	Number of subjects with Response, n (%)	1 (2.8)	0 (0.1)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 6	Number of subjects with Response, n (%)	3 (7.9)	0 (0.3)
	Number of imputations (NRI), n (%)	0 (0.0)	1 (2.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 7	Number of subjects with Response, n (%)	2 (5.3)	0 (0.2)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (5.0)
	Number of imputations (MI), n (%)	2 (5.1)	6 (15.0)
Week 8	Number of subjects with Response, n (%)	2 (5.4)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (5.0)
	Number of imputations (MI), n (%)	2 (5.1)	5 (12.5)
Week 9	Number of subjects with Response, n (%)	1 (2.8)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	5 (12.5)
Week 10	Number of subjects with Response, n (%)	1 (2.8)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	6 (15.0)
Week 11	Number of subjects with Response, n (%)	1 (3.2)	1 (2.7)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	2 (5.1)	5 (12.5)
Week 12	Number of subjects with Response, n (%)	0 (0.9)	0 (0.2)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	3 (7.7)	4 (10.0)
Week 13	Number of subjects with Response, n (%)	3 (8.6)	0 (0.3)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	2 (5.1)	5 (12.5)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 14	Number of subjects with Response, n (%)	2 (6.3)	0 (0.3)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	2 (5.1)	7 (17.5)
Week 15	Number of subjects with Response, n (%)	3 (6.6)	0 (0.6)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	4 (10.3)	7 (17.5)
Week 16	Number of subjects with Response, n (%)	4 (9.0)	1 (1.8)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	4 (10.3)	10 (25.0)
	Adjusted Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.6
Sensitivity Analysis of Body Surface Area (BSA) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	0 (0.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	2 (5.0)
Week 4	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	2 (5.0)
Week 8	Number of subjects with Response, n (%)	2 (5.1)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (5.0)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 12	Number of subjects with Response, n (%)	1 (2.6)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 16	Number of subjects with Response, n (%)	3 (7.7)	1 (2.5)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
	Adjusted Analysis		
	Odds Ratio	3.187	
	95% CI	0.300, 33.890	
	p-value	0.3365	
	Relative Risk	2.842	
	95% CI	0.325, 24.877	
	p-value	0.3453	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 2.4.7
Sensitivity Analysis of Patient Global Impression of Severity (PGIS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=40)
Week 2	Number of subjects with Response, n (%)	2 (6.0)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	2 (5.1)	2 (5.0)
Week 4	Number of subjects with Response, n (%)	4 (10.7)	1 (2.5)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	1 (2.6)	2 (5.0)
Week 12	Number of subjects with Response, n (%)	4 (10.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	3 (7.5)
Week 16	Number of subjects with Response, n (%)	7 (18.4)	1 (2.8)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (7.5)
	Number of imputations (MI), n (%)	1 (2.6)	5 (12.5)
	Adjusted Analysis		
	Odds Ratio	8.392	
	95% CI	0.932, 75.529	
	p-value	0.0577	
	Relative Risk	6.552	
	95% CI	0.842, 50.988	
	p-value	0.0725	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.1
Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	27 (69.2)	17 (43.6)
	Unstratified Analysis		
	Odds Ratio	2.912	
	95% CI	1.150, 7.372	
	p-value	0.0241	
	Relative Risk	1.588	
	95% CI	1.050, 2.402	
	p-value	0.0284	
	Risk Difference	0.256	
	95% CI	0.044, 0.469	
	p-value	0.0181	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.2
Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	27 (69.2)	16 (41.0)
	Unstratified Analysis		
	Odds Ratio	3.234	
	95% CI	1.273, 8.218	
	p-value	0.0136	
	Relative Risk	1.688	
	95% CI	1.097, 2.596	
	p-value	0.0172	
	Risk Difference	0.282	
	95% CI	0.070, 0.494	
	p-value	0.0090	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.3
Serious Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.4
Serious Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.5
Adverse Events of CTCAE Grade >=3
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	3 (7.7)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	7.575	
	95% CI	0.378, 151.723	
	p-value	0.1854	
	Relative Risk	7.000	
	95% CI	0.374, 131.172	
	p-value	0.1931	
	Risk Difference	0.077	
	95% CI	-0.007, 0.161	
	p-value	0.0714	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.6
Adverse Events of CTCAE Grade >=3 (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	2 (5.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	5.267	
	95% CI	0.245, 113.349	
	p-value	0.2887	
	Relative Risk	5.000	
	95% CI	0.248, 100.887	
	p-value	0.2938	
	Risk Difference	0.051	
	95% CI	-0.018, 0.121	
	p-value	0.1465	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.7
Adverse Events of CTCAE Grade <3
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	26 (66.7)	17 (43.6)
	Unstratified Analysis		
	Odds Ratio	2.588	
	95% CI	1.033, 6.486	
	p-value	0.0425	
	Relative Risk	1.529	
	95% CI	1.005, 2.329	
	p-value	0.0476	
	Risk Difference	0.231	
	95% CI	0.016, 0.445	
	p-value	0.0352	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.8
Adverse Events leading to discontinuation of study drug
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	1 (2.6)	1 (2.6)
	Unstratified Analysis		
	Odds Ratio	1.000	
	95% CI	0.060, 16.577	
	p-value	1.0000	
	Relative Risk	1.000	
	95% CI	0.065, 15.426	
	p-value	1.0000	
	Risk Difference	0.000	
	95% CI	-0.070, 0.070	
	p-value	1.0000	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.9
Fatal Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.1
Adverse Events of Special Interest - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.2
Adverse Events of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.3
Adverse Events of Special Interest - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.4
Adverse Events of Special Interest - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.5
Adverse Events of Special Interest - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.6
Adverse Events of Special Interest - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.7
Adverse Events of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.8
Adverse Events of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.9
Adverse Events of Special Interest - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.10
Adverse Events of Special Interest - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	2 (5.1)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	5.267	
	95% CI	0.245, 113.349	
	p-value	0.2887	
	Relative Risk	5.000	
	95% CI	0.248, 100.887	
	p-value	0.2938	
	Risk Difference	0.051	
	95% CI	-0.018, 0.121	
	p-value	0.1465	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.11
Adverse Events of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.12
Adverse Events of Special Interest - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.13
Adverse Events of Special Interest - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.14
Adverse Events of Special Interest - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.15
Adverse Events of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	1 (2.6)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	3.078	
	95% CI	0.122, 77.905	
	p-value	0.4953	
	Relative Risk	3.000	
	95% CI	0.126, 71.455	
	p-value	0.4970	
	Risk Difference	0.026	
	95% CI	-0.024, 0.075	
	p-value	0.3110	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.16
Adverse Events of Special Interest - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.17
Adverse Events of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.10.18
Adverse Events of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.1
Serious Adverse Events of Special Interest - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.2
Serious Adverse Events of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.3
Serious Adverse Events of Special Interest - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.4
Serious Adverse Events of Special Interest - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.5
Serious Adverse Events of Special Interest - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.6
Serious Adverse Events of Special Interest - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.7
Serious Adverse Events of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.8
Serious Adverse Events of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.9
Serious Adverse Events of Special Interest - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.10
Serious Adverse Events of Special Interest - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.11
Serious Adverse Events of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.12
Serious Adverse Events of Special Interest - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.13
Serious Adverse Events of Special Interest - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.14
Serious Adverse Events of Special Interest - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.15
Serious Adverse Events of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.16
Serious Adverse Events of Special Interest - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.17
Serious Adverse Events of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.11.18
Serious Adverse Events of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.1
Adverse Events of Special Interest of CTCAE Grade >=3 - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.2
Adverse Events of Special Interest of CTCAE Grade >=3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.3
Adverse Events of Special Interest of CTCAE Grade >=3 - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.4
Adverse Events of Special Interest of CTCAE Grade >=3 - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.5
Adverse Events of Special Interest of CTCAE Grade >=3 - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.6
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.7
Adverse Events of Special Interest of CTCAE Grade >=3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.8
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.9
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.10
Adverse Events of Special Interest of CTCAE Grade >=3 - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	1 (2.6)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	3.078	
	95% CI	0.122, 77.905	
	p-value	0.4953	
	Relative Risk	3.000	
	95% CI	0.126, 71.455	
	p-value	0.4970	
	Risk Difference	0.026	
	95% CI	-0.024, 0.075	
	p-value	0.3110	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.11
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.12
Adverse Events of Special Interest of CTCAE Grade >=3 - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.13
Adverse Events of Special Interest of CTCAE Grade >=3 - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.14
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.15
Adverse Events of Special Interest of CTCAE Grade >=3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	1 (2.6)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	3.078	
	95% CI	0.122, 77.905	
	p-value	0.4953	
	Relative Risk	3.000	
	95% CI	0.126, 71.455	
	p-value	0.4970	
	Risk Difference	0.026	
	95% CI	-0.024, 0.075	
	p-value	0.3110	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.16
Adverse Events of Special Interest of CTCAE Grade >=3 - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.17
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.12.18
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.1
Adverse Events of Special Interest of CTCAE Grade <3 - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.2
Adverse Events of Special Interest of CTCAE Grade <3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.3
Adverse Events of Special Interest of CTCAE Grade <3 - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.4
Adverse Events of Special Interest of CTCAE Grade <3 - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.5
Adverse Events of Special Interest of CTCAE Grade <3 - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.6
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.7
Adverse Events of Special Interest of CTCAE Grade <3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.8
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.9
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.10
Adverse Events of Special Interest of CTCAE Grade <3 - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	1 (2.6)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	3.078	
	95% CI	0.122, 77.905	
	p-value	0.4953	
	Relative Risk	3.000	
	95% CI	0.126, 71.455	
	p-value	0.4970	
	Risk Difference	0.026	
	95% CI	-0.024, 0.075	
	p-value	0.3110	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.11
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.12
Adverse Events of Special Interest of CTCAE Grade <3 - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.13
Adverse Events of Special Interest of CTCAE Grade <3 - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.14
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.15
Adverse Events of Special Interest of CTCAE Grade <3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.16
Adverse Events of Special Interest of CTCAE Grade <3 - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.17
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.1.13.18
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.2.1
Incidence of Adverse Events leading to discontinuation of study drug by SOC and PT
(Safety Analysis Set)

Up to Visit	System Organ Class (SOC) Preferred Term (PT)	Upadacitinib + TCS (N=39) n (%)	Placebo + TCS (N=39) n (%)
Week 16	Hepatobiliary disorders	1 (2.6)	0 (0.0)
	Hepatic function abnormal	1 (2.6)	0 (0.0)
	Skin and subcutaneous tissue disorders	0 (0.0)	1 (2.6)
	Dermatitis atopic	0 (0.0)	1 (2.6)

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.1 coding dictionary applied.
N: Number of subjects, n: Number of subjects with event
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
SOC: Gastrointestinal disorders	Week 16	Number of subjects with events, n (%)	6 (15.4)	5 (12.8)
		Unstratified Analysis		
		Odds Ratio	1.236	
		95% CI	0.344, 4.446	
		p-value	0.7452	
		Relative Risk	1.200	
		95% CI	0.399, 3.608	
		p-value	0.7454	
		Risk Difference	0.026	
		95% CI	-0.129, 0.18	
		p-value	0.7448	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
SOC: Infections and infestations	Week 16	Number of subjects with events, n (%)	16 (41.0)	11 (28.2)
		Unstratified Analysis		
		Odds Ratio	1.771	
		95% CI	0.688, 4.557	
		p-value	0.2361	
		Relative Risk	1.455	
		95% CI	0.778, 2.721	
		p-value	0.2410	
		Risk Difference	0.128	
		95% CI	-0.081, 0.33	
		p-value	0.2298	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
SOC: Infections and infestations - PT:Nasopharyngitis	Week 16	Number of subjects with events, n (%)	6 (15.4)	3 (7.7)
		Unstratified Analysis		
		Odds Ratio	2.182	
		95% CI	0.505, 9.434	
		p-value	0.2963	
		Relative Risk	2.000	
		95% CI	0.538, 7.434	
		p-value	0.3008	
		Risk Difference	0.077	
		95% CI	-0.064, 0.21	
		p-value	0.2842	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
SOC: Investigations	Week 16	Number of subjects with events, n (%)	3 (7.7)	4 (10.3)
		Unstratified Analysis		
		Odds Ratio	0.729	
		95% CI	0.152, 3.496	
		p-value	0.6929	
		Relative Risk	0.750	
		95% CI	0.180, 3.133	
		p-value	0.6933	
		Risk Difference	-0.026	
		95% CI	-0.152, 0.10	
		p-value	0.6917	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
SOC: Nervous system disorders	Week 16	Number of subjects with events, n (%)	4 (10.3)	3 (7.7)
		Unstratified Analysis		
		Odds Ratio	1.371	
		95% CI	0.286, 6.576	
		p-value	0.6929	
		Relative Risk	1.333	
		95% CI	0.319, 5.570	
		p-value	0.6933	
		Risk Difference	0.026	
		95% CI	-0.101, 0.15	
		p-value	0.6917	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
SOC: Nervous system disorders - PT:Headache	Week 16	Number of subjects with events, n (%)	4 (10.3)	3 (7.7)
		Unstratified Analysis		
		Odds Ratio	1.371	
		95% CI	0.286, 6.576	
		p-value	0.6929	
		Relative Risk	1.333	
		95% CI	0.319, 5.570	
		p-value	0.6933	
		Risk Difference	0.026	
		95% CI	-0.101, 0.15	
		p-value	0.6917	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
SOC: Respiratory, thoracic and mediastinal disorders	Week 16	Number of subjects with events, n (%)	7 (17.9)	1 (2.6)
		Unstratified Analysis		
		Odds Ratio	8.313	
		95% CI	0.971, 71.177	
		p-value	0.0532	
		Relative Risk	7.000	
		95% CI	0.903, 54.253	
		p-value	0.0625	
		Risk Difference	0.154	
		95% CI	0.024, 0.284	
		p-value	0.0206	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
SOC: Skin and subcutaneous tissue disorders	Week 16	Number of subjects with events, n (%)	11 (28.2)	3 (7.7)
		Unstratified Analysis		
		Odds Ratio	4.714	
		95% CI	1.199, 18.530	
		p-value	0.0264	
		Relative Risk	3.667	
		95% CI	1.108, 12.137	
		p-value	0.0334	
		Risk Difference	0.205	
		95% CI	0.041, 0.369	
		p-value	0.0143	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=39)	Placebo + TCS (N=39)
SOC: Skin and subcutaneous tissue disorders - PT:Acne	Week 16	Number of subjects with events, n (%)	5 (12.8)	0 (0.0)
		Unstratified Analysis		
		Odds Ratio	12.594	
		95% CI	0.672, 236.063	
		p-value	0.0903	
		Relative Risk	11.000	
		95% CI	0.629, 192.402	
		p-value	0.1005	
		Risk Difference	0.128	
		95% CI	0.023, 0.233	
		p-value	0.0166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.2
Frequent Serious Adverse Events by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

!!! There are no Observations for this Report !!!

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adolescents (between >= 12 and < 18 years of age at the time of the screening visit)
Table 3.3.3
Frequent Adverse Events of CTCAE Grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

!!! There are no Observations for this Report !!!

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg treatment group.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.1
Demographic and Baseline Characteristics
(ITT_M Population)

		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)	Total (N=785)
Age (years)	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	36.68 (14.16)	37.17 (14.09)	36.84 (14.13)
	Median	33.00	34.50	33.00
	Q1, Q3	25.00, 47.00	25.00, 48.00	25.00, 48.00
	Min, Max	18.00, 74.00	18.00, 75.00	18.00, 75.00
Age Group (years) - n (%)	< 18	0 (0.0)	0 (0.0)	0 (0.0)
	18 - < 40	334 (64.1)	156 (59.1)	490 (62.4)
	40 - < 65	165 (31.7)	94 (35.6)	259 (33.0)
	>=65	22 (4.2)	14 (5.3)	36 (4.6)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Sex - n (%)	Female	199 (38.2)	102 (38.6)	301 (38.3)
	Male	322 (61.8)	162 (61.4)	484 (61.7)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Race - n (%)	White	365 (70.1)	196 (74.2)	561 (71.5)
	Black	24 (4.6)	15 (5.7)	39 (5.0)
	Asian	115 (22.1)	52 (19.7)	167 (21.3)
	Other	17 (3.3)	1 (0.4)	18 (2.3)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Geographic Region - n (%)	US/PR/Canada	179 (34.4)	90 (34.1)	269 (34.3)
	Other	342 (65.6)	174 (65.9)	516 (65.7)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Weight (kg)	n (missing)	521 (0)	263 (1)	784 (1)
	Mean (SD)	76.80 (18.82)	78.04 (20.01)	77.22 (19.23)
	Median	74.30	76.20	75.00
	Q1, Q3	63.10, 86.20	64.00, 88.50	63.50, 87.20
	Min, Max	33.00, 169.00	41.00, 159.70	33.00, 169.00
Weight (kg) - n (%)	< Median (73.11)	248 (47.6)	117 (44.5)	365 (46.6)
	>= Median (73.11)	273 (52.4)	146 (55.5)	419 (53.4)
	Missing	0 (0.0)	1 (0.4)	1 (0.1)
Body Mass Index (kg/m^2)	n (missing)	519 (2)	263 (1)	782 (3)
	Mean (SD)	26.16 (5.78)	26.32 (5.58)	26.21 (5.71)
	Median	25.10	25.60	25.20
	Q1, Q3	22.20, 28.90	22.10, 29.50	22.20, 29.00
	Min, Max	15.30, 55.10	16.00, 58.60	15.30, 58.60
Body Mass Index (kg/m^2) - n (%)	< 25	258 (49.7)	121 (46.0)	379 (48.5)
	25 - < 30	161 (31.0)	85 (32.3)	246 (31.5)
	>= 30	100 (19.3)	57 (21.7)	157 (20.1)
	Missing	2 (0.4)	1 (0.4)	3 (0.4)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.1
Demographic and Baseline Characteristics
(ITT_M Population)

		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)	Total (N=785)
Baseline EASI	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	29.36 (11.95)	30.07 (12.87)	29.60 (12.26)
	Median	25.50	25.55	25.50
	Q1, Q3	20.00, 36.00	19.70, 38.05	20.00, 36.60
	Min, Max	16.00, 69.00	16.00, 69.60	16.00, 69.60
Baseline EASI - n (%)	< Median (25.8)	264 (50.7)	133 (50.4)	397 (50.6)
	>= Median (25.8)	257 (49.3)	131 (49.6)	388 (49.4)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline vIGA-AD	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	3.53 (0.50)	3.53 (0.50)	3.53 (0.50)
	Median	4.00	4.00	4.00
	Q1, Q3	3.00, 4.00	3.00, 4.00	3.00, 4.00
	Min, Max	3.00, 4.00	3.00, 4.00	3.00, 4.00
Baseline vIGA-AD - n (%)	3 (Moderate)	247 (47.4)	123 (46.6)	370 (47.1)
	4 (Severe)	274 (52.6)	141 (53.4)	415 (52.9)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline hsCRP	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	3.69 (8.50)	4.42 (9.54)	3.94 (8.87)
	Median	1.51	1.62	1.54
	Q1, Q3	0.63, 4.03	0.64, 4.00	0.63, 4.03
	Min, Max	0.20, 138.00	0.20, 109.00	0.20, 138.00
Baseline hsCRP - n (%)	< Median (1.41)	243 (46.6)	122 (46.2)	365 (46.5)
	>= Median (1.41)	278 (53.4)	142 (53.8)	420 (53.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Topical Therapy - n (%)	With	503 (96.5)	252 (95.5)	755 (96.2)
	Without	18 (3.5)	12 (4.5)	30 (3.8)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Systemic Therapy - n (%)	With	304 (58.3)	139 (52.7)	443 (56.4)
	Without	217 (41.7)	125 (47.3)	342 (43.6)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Previous Phototherapy - n (%)	With	121 (23.2)	60 (22.7)	181 (23.1)
	Without	400 (76.8)	204 (77.3)	604 (76.9)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Baseline BSA	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	48.18 (22.21)	48.68 (22.81)	48.35 (22.40)
	Median	45.00	43.50	45.00
	Q1, Q3	29.00, 65.00	29.00, 67.30	29.00, 65.00
	Min, Max	12.00, 99.90	12.00, 99.00	12.00, 99.90

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)	Total (N=785)
Worst Pruritus NRS (Weekly Average)	n (missing)	519 (2)	261 (3)	780 (5)
	Mean (SD)	7.29 (1.64)	7.14 (1.61)	7.24 (1.63)
	Median	7.43	7.25	7.40
	Q1, Q3	6.29, 8.43	6.14, 8.14	6.18, 8.33
	Min, Max	0.00, 10.00	0.71, 10.00	0.00, 10.00
Baseline PGIS	n (missing)	517 (4)	262 (2)	779 (6)
	Mean (SD)	4.47 (1.11)	4.59 (1.07)	4.51 (1.10)
	Median	5.00	5.00	5.00
	Q1, Q3	4.00, 5.00	4.00, 5.00	4.00, 5.00
	Min, Max	0.00, 6.00	1.00, 6.00	0.00, 6.00
Disease duration since diagnosis (years)	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	24.58 (15.34)	26.00 (15.56)	25.06 (15.42)
	Median	23.23	24.31	23.82
	Q1, Q3	13.19, 33.25	16.18, 35.89	14.67, 34.28
	Min, Max	0.05, 69.18	0.07, 72.94	0.05, 72.94
Any Allergic Comorbidity - n (%)	With	399 (76.6)	200 (75.8)	599 (76.3)
	Without	122 (23.4)	64 (24.2)	186 (23.7)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Food Allergy - n (%)	With	188 (36.1)	84 (31.8)	272 (34.6)
	Without	333 (63.9)	180 (68.2)	513 (65.4)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Asthma - n (%)	With	239 (45.9)	118 (44.7)	357 (45.5)
	Without	282 (54.1)	146 (55.3)	428 (54.5)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Allergic Rhinitis - n (%)	With	287 (55.1)	151 (57.2)	438 (55.8)
	Without	234 (44.9)	113 (42.8)	347 (44.2)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Eosinophilic Esophagitis - n (%)	With	5 (1.0)	0 (0.0)	5 (0.6)
	Without	516 (99.0)	264 (100.0)	780 (99.4)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)
Medical History of Nasal Polyps - n (%)	With	12 (2.3)	3 (1.1)	15 (1.9)
	Without	509 (97.7)	261 (98.9)	770 (98.1)
	Missing	0 (0.0)	0 (0.0)	0 (0.0)

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
EASI: Eczema Area and Severity Index, vIGA-AD: validated Investigator Global Assessment for Atopic Dermatitis, hsCRP: high sensitivity C-Reactive Protein, BSA: Body Surface Area
NRS: Numeric Rating Scale, PGIS: Head Patient Global Impression of Severity
Geographic regions Japan and China are combined with category Other.
In </>= median categories the median of the Intention-to-treat set of the entire study population is used.
Disease duration since diagnosis is calculated as (date of first dose of study drug - date of initial diagnosis of atopic dermatitis collected in CRF + 1) divided by 365.25
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.2
Subject Disposition
(ITT_M Population)

Status	Upadacitinib + TCS(N=521) n (%)	Placebo + TCS(N=264) n (%)	Total(N=785) n (%)
Received study drug in DB period	521 (100.0)	264 (100.0)	785 (100.0)
Received first rescue medication in DB period	27 (5.2)	71 (26.9)	98 (12.5)
Received first topical rescue medication in DB period	22 (4.2)	67 (25.4)	89 (11.3)
Plain topical corticosteroid in DB period	22 (4.2)	67 (25.4)	89 (11.3)
High potency topical corticosteroid in DB period	22 (4.2)	67 (25.4)	89 (11.3)
Medium potency topical corticosteroid in DB period	0 (0.0)	1 (0.4)	1 (0.1)
Low potency topical corticosteroid in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Topical calcineurin inhibitor in DB period	0 (0.0)	0 (0.0)	0 (0.0)
Other topical therapy in DB period	0 (0.0)	1 (0.4)	1 (0.1)
Received first systemic rescue medication in DB period	7 (1.3)	14 (5.3)	21 (2.7)
Biologic systemic therapy in DB period	0 (0.0)	1 (0.4)	1 (0.1)
Non-biologic immunomodulating systemic therapy in DB period	5 (1.0)	12 (4.5)	17 (2.2)
Other systemic therapy in DB period	2 (0.4)	1 (0.4)	3 (0.4)
Received first rescue phototherapy in DB period	0 (0.0)	1 (0.4)	1 (0.1)
Completed DB period	499 (95.8)	244 (92.4)	743 (94.6)
Ongoing DB Period	5 (1.0)	5 (1.9)	10 (1.3)
Discontinued study in DB period	17 (3.3)	15 (5.7)	32 (4.1)
Primary reason			
Adverse event	2 (0.4)	3 (1.1)	5 (0.6)
Withdrawal of consent	7 (1.3)	6 (2.3)	13 (1.7)
Lost to follow-up	4 (0.8)	3 (1.1)	7 (0.9)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	4 (0.8)	3 (1.1)	7 (0.9)
Completed DB period on study drug	497 (95.4)	244 (92.4)	741 (94.4)
Ongoing DB Period on study drug	4 (0.8)	2 (0.8)	6 (0.8)
Discontinued study drug in DB period	20 (3.8)	18 (6.8)	38 (4.8)
Primary reason			
Adverse event	5 (1.0)	4 (1.5)	9 (1.1)
Withdrawal of consent	5 (1.0)	4 (1.5)	9 (1.1)
Lost to follow-up	3 (0.6)	3 (1.1)	6 (0.8)
Lack of efficacy	2 (0.4)	3 (1.1)	5 (0.6)
EASI score - worsening of 25%	0 (0.0)	0 (0.0)	0 (0.0)
Systemic rescue	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	5 (1.0)	4 (1.5)	9 (1.1)

N: Number of subjects, n: Number of subjects with non-missing status, DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, COVID: Corona Virus Disease
One patient may receive more than one rescue therapy (topical, systemic, phototherapy).
If a patient receives systemic rescue therapy the primary reason for discontinuation of study drug does not necessarily have to be systemic rescue.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.2
Subject Disposition
(ITT_M Population)

Status	Upadacitinib + TCS(N=521) n (%)	Placebo + TCS(N=264) n (%)	Total(N=785) n (%)
Entered BE period	499 (95.8)	244 (92.4)	743 (94.6)
Received study drug in BE period	494 (94.8)	243 (92.0)	737 (93.9)
Received first rescue medication in BE period	34 (6.5)	5 (1.9)	39 (5.0)
Received first topical rescue medication in BE period	30 (5.8)	4 (1.5)	34 (4.3)
Plain topical corticosteroid in BE period	30 (5.8)	4 (1.5)	34 (4.3)
High potency topical corticosteroid in BE period	30 (5.8)	4 (1.5)	34 (4.3)
Medium potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Low potency topical corticosteroid in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Topical calcineurin inhibitor in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Other topical therapy in BE period	1 (0.2)	0 (0.0)	1 (0.1)
Received first systemic rescue medication in BE period	12 (2.3)	3 (1.1)	15 (1.9)
Biologic systemic therapy in BE period	2 (0.4)	1 (0.4)	3 (0.4)
Non-biologic immunomodulating systemic therapy in BE period	8 (1.5)	2 (0.8)	10 (1.3)
Other systemic therapy in BE period	2 (0.4)	0 (0.0)	2 (0.3)
Received first rescue phototherapy in BE period	0 (0.0)	0 (0.0)	0 (0.0)
Ongoing BE Period	471 (90.4)	236 (89.4)	707 (90.1)
Discontinued Study in BE period	28 (5.4)	8 (3.0)	36 (4.6)
Primary reason			
Adverse event	4 (0.8)	2 (0.8)	6 (0.8)
Withdrawal of consent	14 (2.7)	4 (1.5)	18 (2.3)
Lost to follow-up	4 (0.8)	1 (0.4)	5 (0.6)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	6 (1.2)	1 (0.4)	7 (0.9)
Ongoing study drug in BE period	458 (87.9)	236 (89.4)	694 (88.4)
Discontinued study drug in BE Period	36 (6.9)	7 (2.7)	43 (5.5)
Primary reason			
Adverse event	4 (0.8)	1 (0.4)	5 (0.6)
Withdrawal of consent	11 (2.1)	3 (1.1)	14 (1.8)
Lost to follow-up	2 (0.4)	1 (0.4)	3 (0.4)
Lack of efficacy	15 (2.9)	2 (0.8)	17 (2.2)
EASI score - worsening of 25%	0 (0.0)	0 (0.0)	0 (0.0)
Systemic rescue	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 infection	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 logistical restrictions	0 (0.0)	0 (0.0)	0 (0.0)
Other	4 (0.8)	0 (0.0)	4 (0.5)

N: Number of subjects, n: Number of subjects with non-missing status, DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, COVID: Corona Virus Disease
One patient may receive more than one rescue therapy (topical, systemic, phototherapy).
If a patient receives systemic rescue therapy the primary reason for discontinuation of study drug does not necessarily have to be systemic rescue.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.3
Duration of Study and Treatment and Endpoint Observation time at Week 16
(ITT_M Population)

		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)	Total (N=785)
Study duration in DB period (Week 0 - 16) (Weeks)	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	16.14 (1.39)	15.76 (2.07)	16.02 (1.66)
	Median	16.00	16.00	16.00
	Q1, Q3	15.86, 16.14	15.86, 16.14	15.86, 16.14
	Min, Max	5.57, 39.29	0.29, 24.14	0.29, 39.29
Treatment duration in DB period (Week 0 - 16) (Weeks)	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	15.92 (1.20)	15.46 (2.52)	15.76 (1.77)
	Median	16.00	16.00	16.00
	Q1, Q3	15.86, 16.14	15.86, 16.14	15.86, 16.14
	Min, Max	5.57, 21.29	0.29, 19.29	0.29, 21.29
Observation time for safety at Week 16 (Weeks)	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	16.26 (0.84)	15.90 (1.69)	16.14 (1.20)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.29	16.00, 16.29	16.00, 16.29
	Min, Max	9.86, 21.29	4.57, 20.57	4.57, 21.29
Body Surface Area (BSA): Observation time at Week 16 (Weeks)	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	15.95 (1.48)	15.15 (3.17)	15.68 (2.23)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.29	15.86, 16.29	16.00, 16.29
	Min, Max	2.14, 19.71	0.14, 19.43	0.14, 19.71
Eczema Area and Severity Index (EASI): Observation time at Week 16 (Weeks)	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	15.96 (1.47)	15.15 (3.17)	15.69 (2.22)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.29	15.86, 16.29	16.00, 16.29
	Min, Max	2.14, 19.71	0.14, 19.43	0.14, 19.71
Patient Global Impression of Severity (PGIS): Observation time at Week 16 (Weeks)	n (missing)	520 (1)	264 (0)	784 (1)
	Mean (SD)	15.87 (1.91)	15.02 (3.47)	15.59 (2.57)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.29	15.86, 16.29	16.00, 16.29
	Min, Max	0.14, 19.71	0.14, 19.43	0.14, 19.71
Worst Pruritus NRS: Observation time at Week 16 (Weeks)	n (missing)	521 (0)	264 (0)	785 (0)
	Mean (SD)	15.66 (1.79)	14.99 (2.91)	15.44 (2.25)
	Median	16.14	16.14	16.14
	Q1, Q3	16.00, 16.14	15.71, 16.14	15.86, 16.14
	Min, Max	0.14, 16.86	0.14, 16.29	0.14, 16.86

N: Number of subjects, n: Number of subjects with non-missing values, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum
DB: Double-Blind, BE: Blinded Extension, EASI: Eczema Area and Severity Index, NRS: Numeric Rating Scale
Study duration is calculated as (date of first dose of study drug - minimum(date of first dose of study drug in BE period, date of end of study) + 1) divided by 7
Treatment duration is calculated as (date of first dose of study drug - date of last dose of study drug in DB period + 1) divided by 7
Observation time for Safety is calculated as (date of first dose of study drug - minimum(date of first dose of study drug in BE period, date of last dose of study drug in DB period + 30) + 1) divided by 7
Observation time for endpoints is calculated as (date of first dose of study drug - date of last non-missing evaluation in DB period + 1) divided by 7. Evaluations after start of systemic rescue or phototherapy are excluded.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.4
Overview Completion Rates
(ITT_M Population)

Endpoint	Visit	Upadacitinib + TCS(N=521) n (%)	Placebo + TCS(N=264) n (%)
Worst Pruritus Numeric Rating Scale	Baseline	519 (99.6)	261 (98.9)
	Week 1	513 (98.5)	258 (97.7)
	Week 2	510 (97.9)	259 (98.1)
	Week 3	512 (98.3)	258 (97.7)
	Week 4	513 (98.5)	255 (96.6)
	Week 5	515 (98.8)	254 (96.2)
	Week 6	513 (98.5)	250 (94.7)
	Week 7	512 (98.3)	249 (94.3)
	Week 8	506 (97.1)	244 (92.4)
	Week 9	504 (96.7)	245 (92.8)
	Week 10	506 (97.1)	248 (93.9)
	Week 11	504 (96.7)	247 (93.6)
	Week 12	500 (96.0)	246 (93.2)
	Week 13	495 (95.0)	243 (92.0)
	Week 14	491 (94.2)	240 (90.9)
	Week 15	491 (94.2)	239 (90.5)
	Week 16	468 (89.8)	224 (84.8)
Patient Global Impression of Severity (PGIS)	Baseline	517 (99.2)	262 (99.2)
	Week 2	509 (97.7)	257 (97.3)
	Week 4	509 (97.7)	256 (97.0)
	Week 12	510 (97.9)	250 (94.7)
	Week 16	501 (96.2)	245 (92.8)

N: Number of subjects, n: Number of subjects with non missing values
All observed data will be used in the analysis.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 1.5
Overview Missings and Rescue Therapy at Week 16
(ITT_M Population)

		Upadacitinib + TCS(N=521)							Placebo + TCS(N=264)						
		missings			rescue therapy				missings			rescue therapy			
Endpoint	Visit	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)	all (%)	No-COVID (%)	COVID (%)	all (%)	topical (%)	systemic (%)	photo (%)
EASI	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	10 (1.9)	10 (1.9)	0 (0.0)	3 (0.6)	3 (0.6)	0 (0.0)	0 (0.0)	5 (1.9)	5 (1.9)	0 (0.0)	3 (1.1)	3 (1.1)	0 (0.0)	0 (0.0)
	Week 4	7 (1.3)	7 (1.3)	0 (0.0)	7 (1.3)	7 (1.3)	0 (0.0)	0 (0.0)	8 (3.0)	8 (3.0)	0 (0.0)	8 (3.0)	6 (2.3)	2 (0.8)	0 (0.0)
	Week 8	4 (0.8)	4 (0.8)	0 (0.0)	16 (3.1)	15 (2.9)	1 (0.2)	0 (0.0)	7 (2.7)	7 (2.7)	0 (0.0)	49 (18.6)	44 (16.7)	5 (1.9)	0 (0.0)
	Week 12	10 (1.9)	10 (1.9)	0 (0.0)	20 (3.8)	18 (3.5)	2 (0.4)	0 (0.0)	14 (5.3)	14 (5.3)	0 (0.0)	61 (23.1)	52 (19.7)	9 (3.4)	0 (0.0)
	Week 16	17 (3.3)	13 (2.5)	4 (0.8)	23 (4.4)	20 (3.8)	3 (0.6)	0 (0.0)	18 (6.8)	16 (6.1)	2 (0.8)	70 (26.5)	56 (21.2)	13 (4.9)	1 (0.4)
Pruritus	Baseline	2 (0.4)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.1)	3 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 1	8 (1.5)	8 (1.5)	0 (0.0)	3 (0.6)	3 (0.6)	0 (0.0)	0 (0.0)	6 (2.3)	6 (2.3)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
	Week 2	11 (2.1)	11 (2.1)	0 (0.0)	3 (0.6)	3 (0.6)	0 (0.0)	0 (0.0)	5 (1.9)	5 (1.9)	0 (0.0)	3 (1.1)	3 (1.1)	0 (0.0)	0 (0.0)
	Week 3	9 (1.7)	9 (1.7)	0 (0.0)	3 (0.6)	3 (0.6)	0 (0.0)	0 (0.0)	6 (2.3)	6 (2.3)	0 (0.0)	4 (1.5)	4 (1.5)	0 (0.0)	0 (0.0)
	Week 4	8 (1.5)	8 (1.5)	0 (0.0)	5 (1.0)	5 (1.0)	0 (0.0)	0 (0.0)	9 (3.4)	9 (3.4)	0 (0.0)	9 (3.4)	7 (2.7)	2 (0.8)	0 (0.0)
	Week 5	6 (1.2)	6 (1.2)	0 (0.0)	13 (2.5)	13 (2.5)	0 (0.0)	0 (0.0)	10 (3.8)	10 (3.8)	0 (0.0)	44 (16.7)	42 (15.9)	2 (0.8)	0 (0.0)
	Week 6	8 (1.5)	8 (1.5)	0 (0.0)	13 (2.5)	13 (2.5)	0 (0.0)	0 (0.0)	14 (5.3)	14 (5.3)	0 (0.0)	45 (17.0)	42 (15.9)	3 (1.1)	0 (0.0)
	Week 7	9 (1.7)	9 (1.7)	0 (0.0)	13 (2.5)	13 (2.5)	0 (0.0)	0 (0.0)	15 (5.7)	15 (5.7)	0 (0.0)	48 (18.2)	43 (16.3)	5 (1.9)	0 (0.0)
	Week 8	15 (2.9)	15 (2.9)	0 (0.0)	13 (2.5)	13 (2.5)	0 (0.0)	0 (0.0)	20 (7.6)	20 (7.6)	0 (0.0)	48 (18.2)	43 (16.3)	5 (1.9)	0 (0.0)
	Week 9	17 (3.3)	17 (3.3)	0 (0.0)	19 (3.6)	16 (3.1)	3 (0.6)	0 (0.0)	19 (7.2)	19 (7.2)	0 (0.0)	59 (22.3)	52 (19.7)	7 (2.7)	0 (0.0)
	Week 10	15 (2.9)	15 (2.9)	0 (0.0)	19 (3.6)	17 (3.3)	2 (0.4)	0 (0.0)	16 (6.1)	16 (6.1)	0 (0.0)	61 (23.1)	53 (20.1)	8 (3.0)	0 (0.0)
	Week 11	17 (3.3)	17 (3.3)	0 (0.0)	19 (3.6)	17 (3.3)	2 (0.4)	0 (0.0)	17 (6.4)	17 (6.4)	0 (0.0)	61 (23.1)	52 (19.7)	9 (3.4)	0 (0.0)
	Week 12	21 (4.0)	21 (4.0)	0 (0.0)	19 (3.6)	17 (3.3)	2 (0.4)	0 (0.0)	18 (6.8)	18 (6.8)	0 (0.0)	64 (24.2)	53 (20.1)	11 (4.2)	0 (0.0)
	Week 13	26 (5.0)	26 (5.0)	0 (0.0)	20 (3.8)	18 (3.5)	2 (0.4)	0 (0.0)	21 (8.0)	21 (8.0)	0 (0.0)	68 (25.8)	55 (20.8)	12 (4.5)	1 (0.4)
	Week 14	30 (5.8)	30 (5.8)	0 (0.0)	20 (3.8)	18 (3.5)	2 (0.4)	0 (0.0)	24 (9.1)	24 (9.1)	0 (0.0)	67 (25.4)	53 (20.1)	13 (4.9)	1 (0.4)
	Week 15	30 (5.8)	30 (5.8)	0 (0.0)	21 (4.0)	18 (3.5)	3 (0.6)	0 (0.0)	25 (9.5)	25 (9.5)	0 (0.0)	67 (25.4)	53 (20.1)	13 (4.9)	1 (0.4)
	Week 16	53 (10.2)	53 (10.2)	0 (0.0)	21 (4.0)	18 (3.5)	3 (0.6)	0 (0.0)	40 (15.2)	40 (15.2)	0 (0.0)	62 (23.5)	48 (18.2)	13 (4.9)	1 (0.4)
BSA	Baseline	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	10 (1.9)	10 (1.9)	0 (0.0)	3 (0.6)	3 (0.6)	0 (0.0)	0 (0.0)	5 (1.9)	5 (1.9)	0 (0.0)	3 (1.1)	3 (1.1)	0 (0.0)	0 (0.0)
	Week 4	8 (1.5)	8 (1.5)	0 (0.0)	7 (1.3)	7 (1.3)	0 (0.0)	0 (0.0)	8 (3.0)	8 (3.0)	0 (0.0)	8 (3.0)	6 (2.3)	2 (0.8)	0 (0.0)
	Week 8	4 (0.8)	4 (0.8)	0 (0.0)	16 (3.1)	15 (2.9)	1 (0.2)	0 (0.0)	8 (3.0)	8 (3.0)	0 (0.0)	49 (18.6)	44 (16.7)	5 (1.9)	0 (0.0)
	Week 12	10 (1.9)	10 (1.9)	0 (0.0)	20 (3.8)	18 (3.5)	2 (0.4)	0 (0.0)	14 (5.3)	14 (5.3)	0 (0.0)	61 (23.1)	52 (19.7)	9 (3.4)	0 (0.0)
	Week 16	18 (3.5)	14 (2.7)	4 (0.8)	23 (4.4)	20 (3.8)	3 (0.6)	0 (0.0)	18 (6.8)	16 (6.1)	2 (0.8)	70 (26.5)	56 (21.2)	13 (4.9)	1 (0.4)
PGIS	Baseline	4 (0.8)	4 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Week 2	12 (2.3)	12 (2.3)	0 (0.0)	3 (0.6)	3 (0.6)	0 (0.0)	0 (0.0)	7 (2.7)	7 (2.7)	0 (0.0)	3 (1.1)	3 (1.1)	0 (0.0)	0 (0.0)
	Week 4	12 (2.3)	12 (2.3)	0 (0.0)	6 (1.2)	6 (1.2)	0 (0.0)	0 (0.0)	8 (3.0)	8 (3.0)	0 (0.0)	8 (3.0)	6 (2.3)	2 (0.8)	0 (0.0)
	Week 12	11 (2.1)	11 (2.1)	0 (0.0)	21 (4.0)	18 (3.5)	3 (0.6)	0 (0.0)	14 (5.3)	14 (5.3)	0 (0.0)	61 (23.1)	52 (19.7)	9 (3.4)	0 (0.0)
	Week 16	20 (3.8)	16 (3.1)	4 (0.8)	24 (4.6)	20 (3.8)	4 (0.8)	0 (0.0)	19 (7.2)	17 (6.4)	2 (0.8)	70 (26.5)	56 (21.2)	13 (4.9)	1 (0.4)

N: Number of subjects, EASI: Eczema Area and Severity Index, BSA: Body Surface Area, PGIS: Patient Global Impression of Severity
COVID summarizes the number of subjects with missing data due to COVID-19 infection or logistical restriction, No-COVID summarizes all other subjects with missing data.
topical summarizes the number of rescued subjects of the following categories: plain topical corticosteroids, high/medium/low potency topical corticosteroids, topical calcineurin inhibitor, other topical therapy
systemic summarizes the number of rescued subjects of the following categories: biologic systemic therapy, non-biologic immunomodulating systemic therapy, other systemic therapy
photo summarizes the number of rescued subjects with phototherapy.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.1.1
Descriptive Statistics for Mean Values and Change from Baseline - Eczema Area and Severity Index (EASI)
(ITT_M Population)

	Upadacitinib + TCS(N=521)					Placebo + TCS(N=264)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	521	0 (0.0)	29.36 (11.95)			264	0 (0.0)	30.07 (12.87)		
Week 2	511	10 (1.9)	11.20 (9.86)	511	-18.22 (10.18)	259	5 (1.9)	22.91 (14.69)	259	-7.27 (10.54)
Week 4	514	7 (1.3)	6.46 (7.50)	514	-22.88 (10.68)	254	10 (3.8)	20.51 (14.02)	254	-9.64 (11.03)
Week 8	516	5 (1.0)	5.21 (7.14)	516	-24.12 (11.18)	252	12 (4.5)	17.31 (13.63)	252	-12.50 (11.88)
Week 12	509	12 (2.3)	4.73 (7.02)	509	-24.72 (11.08)	241	23 (8.7)	15.95 (14.39)	241	-14.01 (12.63)
Week 16	501	20 (3.8)	4.76 (7.09)	501	-24.64 (11.10)	232	32 (12.1)	15.44 (13.95)	232	-14.51 (12.86)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.1.2
Descriptive Statistics for Mean Values and Change from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT_M Population)

	Upadacitinib + TCS(N=521)					Placebo + TCS(N=264)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	519	2 (0.4)	7.29 (1.64)			261	3 (1.1)	7.14 (1.61)		
Week 1	513	8 (1.5)	5.06 (2.07)	511	-2.24 (1.75)	258	6 (2.3)	6.35 (1.85)	257	-0.81 (1.33)
Week 2	510	11 (2.1)	3.81 (2.27)	508	-3.49 (2.17)	259	5 (1.9)	5.89 (2.10)	257	-1.26 (1.75)
Week 3	512	9 (1.7)	3.08 (2.25)	510	-4.20 (2.33)	258	6 (2.3)	5.53 (2.20)	256	-1.62 (2.00)
Week 4	513	8 (1.5)	2.77 (2.15)	511	-4.52 (2.38)	253	11 (4.2)	5.42 (2.24)	251	-1.72 (2.06)
Week 5	515	6 (1.2)	2.55 (2.16)	513	-4.74 (2.37)	252	12 (4.5)	5.22 (2.20)	251	-1.92 (2.09)
Week 6	513	8 (1.5)	2.53 (2.19)	511	-4.75 (2.43)	247	17 (6.4)	5.17 (2.30)	245	-1.96 (2.27)
Week 7	512	9 (1.7)	2.53 (2.21)	510	-4.75 (2.44)	244	20 (7.6)	5.10 (2.34)	242	-2.03 (2.33)
Week 8	506	15 (2.9)	2.51 (2.23)	504	-4.76 (2.45)	239	25 (9.5)	5.03 (2.36)	239	-2.04 (2.38)
Week 9	501	20 (3.8)	2.40 (2.24)	499	-4.86 (2.46)	238	26 (9.8)	4.86 (2.29)	236	-2.27 (2.30)
Week 10	504	17 (3.3)	2.35 (2.18)	502	-4.91 (2.43)	240	24 (9.1)	4.81 (2.32)	237	-2.33 (2.34)
Week 11	502	19 (3.6)	2.35 (2.22)	500	-4.92 (2.44)	238	26 (9.8)	4.87 (2.42)	235	-2.30 (2.37)
Week 12	498	23 (4.4)	2.37 (2.25)	496	-4.89 (2.48)	235	29 (11.0)	4.89 (2.47)	233	-2.28 (2.43)
Week 13	493	28 (5.4)	2.31 (2.22)	491	-4.97 (2.43)	230	34 (12.9)	4.83 (2.40)	228	-2.34 (2.38)
Week 14	489	32 (6.1)	2.27 (2.21)	488	-5.01 (2.39)	226	38 (14.4)	4.78 (2.40)	223	-2.39 (2.42)
Week 15	488	33 (6.3)	2.36 (2.23)	487	-4.91 (2.42)	225	39 (14.8)	4.82 (2.43)	222	-2.33 (2.38)
Week 16	465	56 (10.7)	2.32 (2.21)	464	-4.94 (2.42)	210	54 (20.5)	4.76 (2.41)	208	-2.37 (2.36)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.1.3
Descriptive Statistics for Mean Values and Change from Baseline - Body Surface Area (BSA)
(ITT_M Population)

	Upadacitinib + TCS(N=521)					Placebo + TCS(N=264)				
	Value at Visit			Change from Baseline		Value at Visit			Change from Baseline	
Visit	n	n_miss (%)	Mean (SD)	n	Mean (SD)	n	n_miss (%)	Mean (SD)	n	Mean (SD)
Baseline	521	0 (0.0)	48.18 (22.21)			264	0 (0.0)	48.68 (22.81)		
Week 2	511	10 (1.9)	24.62 (20.66)	511	-23.69 (18.32)	259	5 (1.9)	39.54 (24.56)	259	-9.21 (15.45)
Week 4	513	8 (1.5)	15.95 (17.96)	513	-32.22 (20.05)	254	10 (3.8)	35.88 (25.06)	254	-12.80 (16.76)
Week 8	516	5 (1.0)	12.19 (15.83)	516	-35.89 (21.28)	251	13 (4.9)	31.33 (24.97)	251	-16.69 (19.09)
Week 12	509	12 (2.3)	10.67 (15.39)	509	-37.69 (20.76)	241	23 (8.7)	29.12 (25.11)	241	-19.38 (20.42)
Week 16	500	21 (4.0)	10.86 (15.49)	500	-37.49 (21.09)	232	32 (12.1)	28.66 (24.37)	232	-19.76 (19.71)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.1.4
Descriptive Statistics for Mean Values and Change from Baseline - Patient Global Impression of Severity (PGIS)
(ITT_M Population)

	Upadacitinib + TCS(N=521)				Placebo + TCS(N=264)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	n	n_miss (%) Mean (SD)	n	Mean (SD)	n	n_miss (%) Mean (SD)	n	Mean (SD)
Baseline	517	4 (0.8) 4.47 (1.11)			262	2 (0.8) 4.59 (1.07)		
Week 2	509	12 (2.3) 2.13 (1.22)	507	-2.35 (1.40)	257	7 (2.7) 3.58 (1.30)	255	-1.02 (1.28)
Week 4	509	12 (2.3) 1.64 (1.14)	506	-2.83 (1.43)	254	10 (3.8) 3.26 (1.37)	252	-1.33 (1.34)
Week 12	507	14 (2.7) 1.68 (1.33)	505	-2.79 (1.54)	241	23 (8.7) 3.11 (1.42)	239	-1.52 (1.49)
Week 16	497	24 (4.6) 1.74 (1.37)	494	-2.73 (1.59)	231	33 (12.5) 3.18 (1.36)	229	-1.43 (1.49)

N: Number of subjects, n: Number of subjects with non missing values, n_miss: Number of subjects with missing values, SD: Standard Deviation
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.2.1
Mixed Effects Model with Repeated Measure for Changes from Baseline - Eczema Area and Severity Index (EASI)
(ITT_M Population)

	Upadacitinib + TCS(N=521)			Placebo + TCS(N=264)						
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)	Difference of LSMeans (95% CI)			p-Value	Hedges` g (95% CI)	p-Value
Week 2			-18.29 (0.41)			-6.98 (0.57)	-11.31 (| -12.69, | -9.93)			
Week 4			-22.98 (0.38)			-9.34 (0.53)	-13.64 (| -14.91, | -12.36)			
Week 8			-24.19 (0.39)			-12.27 (0.55)	-11.91 (| -13.23, | -10.60)			
Week 12			-24.60 (0.40)			-13.35 (0.58)	-11.25 (| -12.63, | -9.87)			
Week 16			-24.54 (0.40)			-13.81 (0.58)	-10.73 (| -12.11, | -9.34)			
Overall up to Week 16	521	0	-22.92 (0.33)	262	2	-11.15 (0.47)	-11.77 (| -12.89, | -10.65)	<.0001	-1.56 (-1.73, -1.40)	<.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.2.2
Mixed Effects Model with Repeated Measure for Changes from Baseline - Worst Pruritus Numeric Rating Scale (WP-NRS)
(ITT_M Population)

	Upadacitinib + TCS(N=521)			Placebo + TCS(N=264)			Difference of LSMeans (95% CI)			p-Value	Hedges` g (95% CI)		p-Value
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)							
Week 1			-2.21 (0.07)			-0.84 (0.10)	-1.37 (	-1.60,	-1.13)				
Week 2			-3.45 (0.09)			-1.29 (0.12)	-2.16 (	-2.45,	-1.86)				
Week 3			-4.19 (0.09)			-1.63 (0.13)	-2.55 (	-2.86,	-2.24)				
Week 4			-4.49 (0.09)			-1.70 (0.13)	-2.79 (	-3.11,	-2.47)				
Week 5			-4.72 (0.09)			-1.91 (0.13)	-2.81 (	-3.13,	-2.50)				
Week 6			-4.73 (0.10)			-1.94 (0.14)	-2.78 (	-3.11,	-2.45)				
Week 7			-4.73 (0.10)			-1.95 (0.14)	-2.78 (	-3.11,	-2.44)				
Week 8			-4.73 (0.10)			-2.00 (0.14)	-2.73 (	-3.07,	-2.39)				
Week 9			-4.84 (0.10)			-2.15 (0.14)	-2.69 (	-3.03,	-2.35)				
Week 10			-4.86 (0.10)			-2.23 (0.14)	-2.63 (	-2.97,	-2.29)				
Week 11			-4.88 (0.10)			-2.18 (0.14)	-2.70 (	-3.04,	-2.36)				
Week 12			-4.85 (0.10)			-2.18 (0.15)	-2.66 (	-3.01,	-2.32)				
Week 13			-4.94 (0.10)			-2.27 (0.14)	-2.67 (	-3.01,	-2.33)				
Week 14			-4.96 (0.10)			-2.30 (0.14)	-2.66 (	-3.00,	-2.32)				
Week 15			-4.88 (0.10)			-2.23 (0.14)	-2.65 (	-2.99,	-2.31)				
Week 16			-4.88 (0.10)			-2.19 (0.14)	-2.69 (	-3.04,	-2.35)				
Overall up to Week 16	517	4	-4.52 (0.08)	260	4	-1.94 (0.12)	-2.58 (	-2.87,	-2.30)	<.0001	-1.34 (-1.50,	-1.18)	<.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.2.3
Mixed Effects Model with Repeated Measure for Changes from Baseline - Body Surface Area (BSA)
(ITT_M Population)

Visit	Upadacitinib + TCS(N=521)			Placebo + TCS(N=264)			Difference of LSMeans (95% CI)			p-Value	Hedges` g (95% CI)		p-Value
	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)							
Week 2			-23.74 (0.71)			-9.10 (1.00)	-14.64 (	-17.05,	-12.23)				
Week 4			-32.29 (0.72)			-12.73 (1.02)	-19.57 (	-22.01,	-17.12)				
Week 8			-35.90 (0.74)			-16.47 (1.05)	-19.43 (	-21.95,	-16.91)				
Week 12			-37.30 (0.74)			-18.64 (1.07)	-18.66 (	-21.22,	-16.11)				
Week 16			-37.06 (0.74)			-19.03 (1.07)	-18.03 (	-20.57,	-15.48)				
Overall up to Week 16	521	0	-33.26 (0.61)	262	2	-15.20 (0.86)	-18.06 (	-20.13,	-16.00)	<.0001	-1.30 (-1.46,	-1.14)	<.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.2.4
Mixed Effects Model with Repeated Measure for Changes from Baseline - Patient Global Impression of Severity (PGIS)
(ITT_M Population)

	Upadacitinib + TCS(N=521)			Placebo + TCS(N=264)			Difference of LSMeans (95% CI)					
Visit	N*	N**	LSMean (SE)	N*	N**	LSMean (SE)				p-Value	Hedges` g (95% CI)	p-Value
Week 2			-2.38 (0.05)			-0.97 (0.07)	-1.40 (	-1.58,	-1.23)			
Week 4			-2.86 (0.05)			-1.27 (0.07)	-1.59 (	-1.77,	-1.42)			
Week 12			-2.81 (0.06)			-1.41 (0.08)	-1.40 (	-1.60,	-1.20)			
Week 16			-2.76 (0.06)			-1.32 (0.09)	-1.43 (	-1.64,	-1.23)			
Overall up to Week 16	516	4	-2.70 (0.04)	260	4	-1.24 (0.06)	-1.46 (	-1.61,	-1.31)	<.0001	-1.43 (-1.60, -1.27)	<.0001

N: Number of subjects, N*: Number of subjects included in model, N**: Number of subjects not included in model, LS: Least Squares, SE: Standard Error, CI: Confidence Interval, NE: Not estimable
No Imputation Method: all observed data will be used in the analysis, except that measurements after systemic rescue or phototherapy will be treated as missing.
Mixed effects model on change from baseline adjusted for baseline score, treatment group, vIGA-AD categories, visit and interaction between treatment and visit.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.1
Eczema Area and Severity Index (EASI) 75 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	195 (37.4)	16 (6.1)
	Number of imputations (NRI), n (%)	10 (1.9)	5 (1.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	347 (66.6)	35 (13.3)
	Number of imputations (NRI), n (%)	7 (1.3)	10 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	391 (75.0)	59 (22.3)
	Number of imputations (NRI), n (%)	5 (1.0)	12 (4.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	405 (77.7)	78 (29.5)
	Number of imputations (NRI), n (%)	12 (2.3)	23 (8.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	388 (74.4)	83 (31.6)
	Number of imputations (NRI), n (%)	16 (3.1)	30 (11.4)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.8)	2 (0.8)
	Adjusted Analysis		
	Odds Ratio	6.352	
	95% CI	4.576, 8.818	
	p-value	<.0001	
	Relative Risk	2.356	
	95% CI	1.958, 2.835	
	p-value	<.0001	
	Risk Difference	0.428	
	95% CI	0.360, 0.495	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.2
Eczema Area and Severity Index (EASI) 90 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	72 (13.8)	7 (2.7)
	Number of imputations (NRI), n (%)	10 (1.9)	5 (1.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	191 (36.7)	11 (4.2)
	Number of imputations (NRI), n (%)	7 (1.3)	10 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	261 (50.1)	17 (6.4)
	Number of imputations (NRI), n (%)	5 (1.0)	12 (4.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	276 (53.0)	32 (12.1)
	Number of imputations (NRI), n (%)	12 (2.3)	23 (8.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	281 (53.9)	38 (14.5)
	Number of imputations (NRI), n (%)	16 (3.1)	30 (11.4)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.8)	2 (0.8)
	Adjusted Analysis		
	Odds Ratio	7.093	
	95% CI	4.808, 10.464	
	p-value	<.0001	
	Relative Risk	3.729	
	95% CI	2.752, 5.053	
	p-value	<.0001	
	Risk Difference	0.383	
	95% CI	0.322, 0.444	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.3
Eczema Area and Severity Index (EASI) 100 response (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	14 (2.7)	0 (0.0)
	Number of imputations (NRI), n (%)	10 (1.9)	5 (1.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	48 (9.2)	3 (1.1)
	Number of imputations (NRI), n (%)	7 (1.3)	10 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	76 (14.6)	2 (0.8)
	Number of imputations (NRI), n (%)	5 (1.0)	12 (4.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	94 (18.0)	5 (1.9)
	Number of imputations (NRI), n (%)	12 (2.3)	23 (8.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	91 (17.5)	4 (1.5)
	Number of imputations (NRI), n (%)	16 (3.1)	30 (11.4)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.8)	2 (0.8)
	Adjusted Analysis		
	Odds Ratio	13.891	
	95% CI	5.038, 38.301	
	p-value	<.0001	
	Relative Risk	11.492	
	95% CI	4.272, 30.916	
	p-value	<.0001	
	Risk Difference	0.153	
	95% CI	0.114, 0.191	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 1	Number of subjects with Response, n (%)	83 (15.9)	6 (2.3)
	Number of imputations (NRI), n (%)	8 (1.5)	6 (2.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	202 (38.8)	24 (9.1)
	Number of imputations (NRI), n (%)	11 (2.1)	5 (1.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 3	Number of subjects with Response, n (%)	281 (53.9)	32 (12.1)
	Number of imputations (NRI), n (%)	9 (1.7)	6 (2.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	314 (60.3)	37 (14.0)
	Number of imputations (NRI), n (%)	8 (1.5)	11 (4.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 5	Number of subjects with Response, n (%)	323 (62.0)	42 (15.9)
	Number of imputations (NRI), n (%)	6 (1.2)	12 (4.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 6	Number of subjects with Response, n (%)	327 (62.8)	41 (15.5)
	Number of imputations (NRI), n (%)	8 (1.5)	17 (6.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 7	Number of subjects with Response, n (%)	330 (63.3)	44 (16.7)
	Number of imputations (NRI), n (%)	9 (1.7)	20 (7.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	329 (63.1)	46 (17.4)
	Number of imputations (NRI), n (%)	15 (2.9)	25 (9.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 9	Number of subjects with Response, n (%)	337 (64.7)	53 (20.1)
	Number of imputations (NRI), n (%)	20 (3.8)	26 (9.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 10	Number of subjects with Response, n (%)	343 (65.8)	55 (20.8)
	Number of imputations (NRI), n (%)	17 (3.3)	24 (9.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 11	Number of subjects with Response, n (%)	346 (66.4)	57 (21.6)
	Number of imputations (NRI), n (%)	19 (3.6)	26 (9.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	334 (64.1)	58 (22.0)
	Number of imputations (NRI), n (%)	23 (4.4)	29 (11.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 13	Number of subjects with Response, n (%)	333 (63.9)	52 (19.7)
	Number of imputations (NRI), n (%)	28 (5.4)	34 (12.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.4
Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 14	Number of subjects with Response, n (%)	337 (64.7)	57 (21.6)
	Number of imputations (NRI), n (%)	32 (6.1)	38 (14.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 15	Number of subjects with Response, n (%)	331 (63.5)	50 (18.9)
	Number of imputations (NRI), n (%)	33 (6.3)	39 (14.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	312 (59.9)	48 (18.2)
	Number of imputations (NRI), n (%)	56 (10.7)	54 (20.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	6.720	
	95% CI	4.695, 9.618	
	p-value	<.0001	
	Relative Risk	3.294	
	95% CI	2.526, 4.295	
	p-value	<.0001	
	Risk Difference	0.418	
	95% CI	0.355, 0.480	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 1	Number of subjects with Response, n (%)	1 (0.2)	0 (0.0)
	Number of imputations (NRI), n (%)	8 (1.5)	6 (2.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 2	Number of subjects with Response, n (%)	9 (1.7)	0 (0.0)
	Number of imputations (NRI), n (%)	11 (2.1)	5 (1.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 3	Number of subjects with Response, n (%)	23 (4.4)	1 (0.4)
	Number of imputations (NRI), n (%)	9 (1.7)	6 (2.3)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	41 (7.9)	0 (0.0)
	Number of imputations (NRI), n (%)	8 (1.5)	11 (4.2)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 5	Number of subjects with Response, n (%)	51 (9.8)	1 (0.4)
	Number of imputations (NRI), n (%)	6 (1.2)	12 (4.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 6	Number of subjects with Response, n (%)	63 (12.1)	1 (0.4)
	Number of imputations (NRI), n (%)	8 (1.5)	17 (6.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 7	Number of subjects with Response, n (%)	55 (10.6)	1 (0.4)
	Number of imputations (NRI), n (%)	9 (1.7)	20 (7.6)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	63 (12.1)	3 (1.1)
	Number of imputations (NRI), n (%)	15 (2.9)	25 (9.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 9	Number of subjects with Response, n (%)	76 (14.6)	1 (0.4)
	Number of imputations (NRI), n (%)	20 (3.8)	26 (9.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 10	Number of subjects with Response, n (%)	73 (14.0)	4 (1.5)
	Number of imputations (NRI), n (%)	17 (3.3)	24 (9.1)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 11	Number of subjects with Response, n (%)	82 (15.7)	3 (1.1)
	Number of imputations (NRI), n (%)	19 (3.6)	26 (9.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	82 (15.7)	2 (0.8)
	Number of imputations (NRI), n (%)	23 (4.4)	29 (11.0)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 13	Number of subjects with Response, n (%)	84 (16.1)	2 (0.8)
	Number of imputations (NRI), n (%)	28 (5.4)	34 (12.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.5
Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 14	Number of subjects with Response, n (%)	88 (16.9)	3 (1.1)
	Number of imputations (NRI), n (%)	32 (6.1)	38 (14.4)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 15	Number of subjects with Response, n (%)	86 (16.5)	2 (0.8)
	Number of imputations (NRI), n (%)	33 (6.3)	39 (14.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	87 (16.7)	5 (1.9)
	Number of imputations (NRI), n (%)	56 (10.7)	54 (20.5)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
	Adjusted Analysis		
	Odds Ratio	10.420	
	95% CI	4.173, 26.018	
	p-value	<.0001	
	Relative Risk	8.786	
	95% CI	3.613, 21.369	
	p-value	<.0001	
	Risk Difference	0.144	
	95% CI	0.107, 0.181	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.6
Body Surface Area (BSA) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	14 (2.7)	0 (0.0)
	Number of imputations (NRI), n (%)	10 (1.9)	5 (1.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	48 (9.2)	3 (1.1)
	Number of imputations (NRI), n (%)	8 (1.5)	10 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 8	Number of subjects with Response, n (%)	76 (14.6)	2 (0.8)
	Number of imputations (NRI), n (%)	5 (1.0)	13 (4.9)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	93 (17.9)	5 (1.9)
	Number of imputations (NRI), n (%)	12 (2.3)	23 (8.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	91 (17.5)	4 (1.5)
	Number of imputations (NRI), n (%)	17 (3.3)	30 (11.4)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.8)	2 (0.8)
	Adjusted Analysis		
	Odds Ratio	13.891	
	95% CI	5.038, 38.301	
	p-value	<.0001	
	Relative Risk	11.492	
	95% CI	4.272, 30.916	
	p-value	<.0001	
	Risk Difference	0.153	
	95% CI	0.114, 0.191	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.3.7
Patient Global Impression of Severity (PGIS) = 0 (modified NRI-C)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	22 (4.2)	1 (0.4)
	Number of imputations (NRI), n (%)	12 (2.3)	7 (2.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 4	Number of subjects with Response, n (%)	52 (10.0)	3 (1.1)
	Number of imputations (NRI), n (%)	12 (2.3)	10 (3.8)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 12	Number of subjects with Response, n (%)	81 (15.5)	1 (0.4)
	Number of imputations (NRI), n (%)	14 (2.7)	23 (8.7)
	Number of imputations due to COVID-19 (MI), n (%)	0 (0.0)	0 (0.0)
Week 16	Number of subjects with Response, n (%)	87 (16.7)	1 (0.4)
	Number of imputations (NRI), n (%)	20 (3.8)	31 (11.7)
	Number of imputations due to COVID-19 (MI), n (%)	4 (0.8)	2 (0.8)
	Adjusted Analysis		
	Odds Ratio	50.638	
	95% CI	7.020, 365.292	
	p-value	<.0001	
	Relative Risk	41.799	
	95% CI	5.867, 297.79	
	p-value	0.0002	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, modified NRI-C: Non-responder imputation incorporating multiple imputation (MI) to handle missing data due to COVID-19
Missings not due to COVID-19 will be imputed as non-responders, except when the subject is a responder both before and after the visit window. Then the subject will be categorized as a responder for the missing visit. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.1
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 75 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	198 (38.0)	16 (6.2)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (1.9)	5 (1.9)
Week 4	Number of subjects with Response, n (%)	347 (66.7)	36 (13.6)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (0.8)
	Number of imputations (MI), n (%)	7 (1.3)	8 (3.0)
Week 8	Number of subjects with Response, n (%)	392 (75.2)	60 (22.9)
	Number of imputations (NRI), n (%)	1 (0.2)	5 (1.9)
	Number of imputations (MI), n (%)	4 (0.8)	7 (2.7)
Week 12	Number of subjects with Response, n (%)	408 (78.2)	80 (30.4)
	Number of imputations (NRI), n (%)	2 (0.4)	9 (3.4)
	Number of imputations (MI), n (%)	10 (1.9)	14 (5.3)
Week 16	Number of subjects with Response, n (%)	393 (75.4)	86 (32.6)
	Number of imputations (NRI), n (%)	3 (0.6)	14 (5.3)
	Number of imputations (MI), n (%)	17 (3.3)	18 (6.8)
	Adjusted Analysis		
	Odds Ratio	6.379	
	95% CI	4.568, 8.909	
	p-value	<.0001	
	Relative Risk	2.311	
	95% CI	1.924, 2.777	
	p-value	<.0001	
	Risk Difference	0.427	
	95% CI	0.358, 0.495	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.2
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 90 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	73 (14.0)	7 (2.7)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (1.9)	5 (1.9)
Week 4	Number of subjects with Response, n (%)	190 (36.5)	11 (4.3)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (0.8)
	Number of imputations (MI), n (%)	7 (1.3)	8 (3.0)
Week 8	Number of subjects with Response, n (%)	261 (50.2)	17 (6.6)
	Number of imputations (NRI), n (%)	1 (0.2)	5 (1.9)
	Number of imputations (MI), n (%)	4 (0.8)	7 (2.7)
Week 12	Number of subjects with Response, n (%)	277 (53.2)	33 (12.4)
	Number of imputations (NRI), n (%)	2 (0.4)	9 (3.4)
	Number of imputations (MI), n (%)	10 (1.9)	14 (5.3)
Week 16	Number of subjects with Response, n (%)	282 (54.1)	39 (14.7)
	Number of imputations (NRI), n (%)	3 (0.6)	14 (5.3)
	Number of imputations (MI), n (%)	17 (3.3)	18 (6.8)
	Adjusted Analysis		
	Odds Ratio	7.049	
	95% CI	4.763, 10.431	
	p-value	<.0001	
	Relative Risk	3.688	
	95% CI	2.718, 5.003	
	p-value	<.0001	
	Risk Difference	0.383	
	95% CI	0.321, 0.444	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.3
Sensitivity Analysis of Eczema Area and Severity Index (EASI) 100 response (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	14 (2.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (1.9)	5 (1.9)
Week 4	Number of subjects with Response, n (%)	48 (9.2)	3 (1.2)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (0.8)
	Number of imputations (MI), n (%)	7 (1.3)	8 (3.0)
Week 8	Number of subjects with Response, n (%)	76 (14.6)	2 (0.8)
	Number of imputations (NRI), n (%)	1 (0.2)	5 (1.9)
	Number of imputations (MI), n (%)	4 (0.8)	7 (2.7)
Week 12	Number of subjects with Response, n (%)	94 (18.0)	5 (1.9)
	Number of imputations (NRI), n (%)	2 (0.4)	9 (3.4)
	Number of imputations (MI), n (%)	10 (1.9)	14 (5.3)
Week 16	Number of subjects with Response, n (%)	91 (17.5)	4 (1.5)
	Number of imputations (NRI), n (%)	3 (0.6)	14 (5.3)
	Number of imputations (MI), n (%)	17 (3.3)	18 (6.8)
	Adjusted Analysis		
	Odds Ratio	13.806	
	95% CI	5.006, 38.077	
	p-value	<.0001	
	Relative Risk	11.419	
	95% CI	4.244, 30.724	
	p-value	<.0001	
	Risk Difference	0.153	
	95% CI	0.114, 0.191	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 1	Number of subjects with Response, n (%)	83 (16.0)	6 (2.4)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	8 (1.5)	6 (2.3)
Week 2	Number of subjects with Response, n (%)	205 (39.3)	24 (9.2)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	11 (2.1)	5 (1.9)
Week 3	Number of subjects with Response, n (%)	284 (54.4)	32 (12.2)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	9 (1.7)	6 (2.3)
Week 4	Number of subjects with Response, n (%)	316 (60.7)	37 (14.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (0.8)
	Number of imputations (MI), n (%)	8 (1.5)	9 (3.4)
Week 5	Number of subjects with Response, n (%)	326 (62.6)	43 (16.4)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (0.8)
	Number of imputations (MI), n (%)	6 (1.2)	10 (3.8)
Week 6	Number of subjects with Response, n (%)	330 (63.4)	42 (16.0)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (1.1)
	Number of imputations (MI), n (%)	8 (1.5)	14 (5.3)
Week 7	Number of subjects with Response, n (%)	334 (64.1)	45 (17.1)
	Number of imputations (NRI), n (%)	0 (0.0)	5 (1.9)
	Number of imputations (MI), n (%)	9 (1.7)	15 (5.7)
Week 8	Number of subjects with Response, n (%)	337 (64.6)	47 (17.9)
	Number of imputations (NRI), n (%)	0 (0.0)	5 (1.9)
	Number of imputations (MI), n (%)	15 (2.9)	20 (7.6)
Week 9	Number of subjects with Response, n (%)	344 (66.0)	55 (20.7)
	Number of imputations (NRI), n (%)	3 (0.6)	7 (2.7)
	Number of imputations (MI), n (%)	17 (3.3)	19 (7.2)
Week 10	Number of subjects with Response, n (%)	349 (66.9)	56 (21.0)
	Number of imputations (NRI), n (%)	2 (0.4)	8 (3.0)
	Number of imputations (MI), n (%)	15 (2.9)	16 (6.1)
Week 11	Number of subjects with Response, n (%)	354 (68.0)	58 (21.9)
	Number of imputations (NRI), n (%)	2 (0.4)	9 (3.4)
	Number of imputations (MI), n (%)	17 (3.3)	17 (6.4)
Week 12	Number of subjects with Response, n (%)	344 (66.0)	59 (22.2)
	Number of imputations (NRI), n (%)	2 (0.4)	11 (4.2)
	Number of imputations (MI), n (%)	21 (4.0)	18 (6.8)
Week 13	Number of subjects with Response, n (%)	347 (66.6)	54 (20.3)
	Number of imputations (NRI), n (%)	2 (0.4)	13 (4.9)
	Number of imputations (MI), n (%)	26 (5.0)	21 (8.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.4
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) improvement from baseline >= 4 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 14	Number of subjects with Response, n (%)	354 (68.0)	59 (22.3)
	Number of imputations (NRI), n (%)	2 (0.4)	14 (5.3)
	Number of imputations (MI), n (%)	30 (5.8)	24 (9.1)
Week 15	Number of subjects with Response, n (%)	349 (66.9)	52 (19.6)
	Number of imputations (NRI), n (%)	3 (0.6)	14 (5.3)
	Number of imputations (MI), n (%)	30 (5.8)	25 (9.5)
Week 16	Number of subjects with Response, n (%)	344 (65.9)	51 (19.2)
	Number of imputations (NRI), n (%)	3 (0.6)	14 (5.3)
	Number of imputations (MI), n (%)	53 (10.2)	40 (15.2)
	Adjusted Analysis		
	Odds Ratio	8.124	
	95% CI	5.638, 11.707	
	p-value	<.0001	
	Relative Risk	3.428	
	95% CI	2.643, 4.447	
	p-value	<.0001	
	Risk Difference	0.467	
	95% CI	0.402, 0.531	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 1	Number of subjects with Response, n (%)	1 (0.2)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	8 (1.5)	6 (2.3)
Week 2	Number of subjects with Response, n (%)	9 (1.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	11 (2.1)	5 (1.9)
Week 3	Number of subjects with Response, n (%)	23 (4.4)	1 (0.4)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	9 (1.7)	6 (2.3)
Week 4	Number of subjects with Response, n (%)	40 (7.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (0.8)
	Number of imputations (MI), n (%)	8 (1.5)	9 (3.4)
Week 5	Number of subjects with Response, n (%)	51 (9.8)	1 (0.4)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (0.8)
	Number of imputations (MI), n (%)	6 (1.2)	10 (3.8)
Week 6	Number of subjects with Response, n (%)	63 (12.1)	1 (0.4)
	Number of imputations (NRI), n (%)	0 (0.0)	3 (1.1)
	Number of imputations (MI), n (%)	8 (1.5)	14 (5.3)
Week 7	Number of subjects with Response, n (%)	55 (10.6)	1 (0.4)
	Number of imputations (NRI), n (%)	0 (0.0)	5 (1.9)
	Number of imputations (MI), n (%)	9 (1.7)	15 (5.7)
Week 8	Number of subjects with Response, n (%)	63 (12.1)	3 (1.1)
	Number of imputations (NRI), n (%)	0 (0.0)	5 (1.9)
	Number of imputations (MI), n (%)	15 (2.9)	20 (7.6)
Week 9	Number of subjects with Response, n (%)	76 (14.6)	1 (0.4)
	Number of imputations (NRI), n (%)	3 (0.6)	7 (2.7)
	Number of imputations (MI), n (%)	17 (3.3)	19 (7.2)
Week 10	Number of subjects with Response, n (%)	73 (14.0)	4 (1.5)
	Number of imputations (NRI), n (%)	2 (0.4)	8 (3.0)
	Number of imputations (MI), n (%)	15 (2.9)	16 (6.1)
Week 11	Number of subjects with Response, n (%)	82 (15.7)	3 (1.1)
	Number of imputations (NRI), n (%)	2 (0.4)	9 (3.4)
	Number of imputations (MI), n (%)	17 (3.3)	17 (6.4)
Week 12	Number of subjects with Response, n (%)	82 (15.7)	2 (0.8)
	Number of imputations (NRI), n (%)	2 (0.4)	11 (4.2)
	Number of imputations (MI), n (%)	21 (4.0)	18 (6.8)
Week 13	Number of subjects with Response, n (%)	83 (15.9)	2 (0.8)
	Number of imputations (NRI), n (%)	2 (0.4)	13 (4.9)
	Number of imputations (MI), n (%)	26 (5.0)	21 (8.0)

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.5
Sensitivity Analysis of Worst Pruritus Numeric Rating Scale (WP-NRS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 14	Number of subjects with Response, n (%)	87 (16.7)	3 (1.1)
	Number of imputations (NRI), n (%)	2 (0.4)	14 (5.3)
	Number of imputations (MI), n (%)	30 (5.8)	24 (9.1)
Week 15	Number of subjects with Response, n (%)	85 (16.3)	2 (0.8)
	Number of imputations (NRI), n (%)	3 (0.6)	14 (5.3)
	Number of imputations (MI), n (%)	30 (5.8)	25 (9.5)
Week 16	Number of subjects with Response, n (%)	87 (16.7)	5 (1.9)
	Number of imputations (NRI), n (%)	3 (0.6)	14 (5.3)
	Number of imputations (MI), n (%)	53 (10.2)	40 (15.2)
	Adjusted Analysis		
	Odds Ratio	10.420	
	95% CI	4.173, 26.018	
	p-value	<.0001	
	Relative Risk	8.786	
	95% CI	3.613, 21.369	
	p-value	<.0001	
	Risk Difference	0.144	
	95% CI	0.107, 0.181	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.6
Sensitivity Analysis of Body Surface Area (BSA) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	14 (2.7)	0 (0.0)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	10 (1.9)	5 (1.9)
Week 4	Number of subjects with Response, n (%)	48 (9.2)	3 (1.1)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (0.8)
	Number of imputations (MI), n (%)	8 (1.5)	8 (3.0)
Week 8	Number of subjects with Response, n (%)	76 (14.6)	2 (0.8)
	Number of imputations (NRI), n (%)	1 (0.2)	5 (1.9)
	Number of imputations (MI), n (%)	4 (0.8)	8 (3.0)
Week 12	Number of subjects with Response, n (%)	93 (17.9)	5 (1.9)
	Number of imputations (NRI), n (%)	2 (0.4)	9 (3.4)
	Number of imputations (MI), n (%)	10 (1.9)	14 (5.3)
Week 16	Number of subjects with Response, n (%)	91 (17.5)	4 (1.5)
	Number of imputations (NRI), n (%)	3 (0.6)	14 (5.3)
	Number of imputations (MI), n (%)	18 (3.5)	18 (6.8)
	Adjusted Analysis		
	Odds Ratio	13.904	
	95% CI	5.043, 38.338	
	p-value	<.0001	
	Relative Risk	11.501	
	95% CI	4.275, 30.938	
	p-value	<.0001	
	Risk Difference	0.153	
	95% CI	0.114, 0.191	
	p-value	<.0001	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 2.4.7
Sensitivity Analysis of Patient Global Impression of Severity (PGIS) = 0 (NRI/MI)
(ITT_M Population)

Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 2	Number of subjects with Response, n (%)	23 (4.4)	1 (0.4)
	Number of imputations (NRI), n (%)	0 (0.0)	0 (0.0)
	Number of imputations (MI), n (%)	12 (2.3)	7 (2.7)
Week 4	Number of subjects with Response, n (%)	54 (10.3)	3 (1.2)
	Number of imputations (NRI), n (%)	0 (0.0)	2 (0.8)
	Number of imputations (MI), n (%)	12 (2.3)	8 (3.0)
Week 12	Number of subjects with Response, n (%)	83 (15.9)	1 (0.5)
	Number of imputations (NRI), n (%)	3 (0.6)	9 (3.4)
	Number of imputations (MI), n (%)	11 (2.1)	14 (5.3)
Week 16	Number of subjects with Response, n (%)	89 (17.2)	1 (0.5)
	Number of imputations (NRI), n (%)	4 (0.8)	14 (5.3)
	Number of imputations (MI), n (%)	20 (3.8)	19 (7.2)
	Adjusted Analysis		
	Odds Ratio	47.212	
	95% CI	6.513, 342.250	
	p-value	0.0001	
	Relative Risk	38.739	
	95% CI	5.423, 276.71	
	p-value	0.0003	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

N: Number of subjects, CI: Confidence Interval, NE: Not estimable, NRI: Non-responder Imputation, MI: Multiple Imputation
Missing values will be imputed by multiple imputation. Values after systemic rescue or phototherapy will be counted as non-responders.
The number of subjects with response is displayed as integer. Percentages are based on the exact value for number of subjects with response after imputation.
Adjusted Odds Ratio, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and logit-link.
Adjusted Relative Risk, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and log-link.
Adjusted Risk Difference, CI and p-value based on a generalized linear model with treatment and vIGA-AD categories as covariates and identity-link.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.1
Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	357 (68.5)	173 (65.5)
	Unstratified Analysis		
	Odds Ratio	1.145	
	95% CI	0.836, 1.567	
	p-value	0.3979	
	Relative Risk	1.046	
	95% CI	0.941, 1.162	
	p-value	0.4050	
	Risk Difference	0.030	
	95% CI	-0.040, 0.100	
	p-value	0.4011	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.2
Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	354 (67.9)	167 (63.3)
	Unstratified Analysis		
	Odds Ratio	1.231	
	95% CI	0.903, 1.680	
	p-value	0.1893	
	Relative Risk	1.074	
	95% CI	0.963, 1.198	
	p-value	0.1995	
	Risk Difference	0.047	
	95% CI	-0.024, 0.118	
	p-value	0.1932	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.3
Serious Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	11 (2.1)	9 (3.4)
	Unstratified Analysis		
	Odds Ratio	0.611	
	95% CI	0.250, 1.494	
	p-value	0.2801	
	Relative Risk	0.619	
	95% CI	0.260, 1.476	
	p-value	0.2795	
	Risk Difference	-0.013	
	95% CI	-0.038, 0.012	
	p-value	0.3115	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.4
Serious Adverse Events (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	11 (2.1)	9 (3.4)
	Unstratified Analysis		
	Odds Ratio	0.611	
	95% CI	0.250, 1.494	
	p-value	0.2801	
	Relative Risk	0.619	
	95% CI	0.260, 1.476	
	p-value	0.2795	
	Risk Difference	-0.013	
	95% CI	-0.038, 0.012	
	p-value	0.3115	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.5
Adverse Events of CTCAE Grade >=3
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	23 (4.4)	15 (5.7)
	Unstratified Analysis		
	Odds Ratio	0.767	
	95% CI	0.393, 1.495	
	p-value	0.4356	
	Relative Risk	0.777	
	95% CI	0.412, 1.464	
	p-value	0.4349	
	Risk Difference	-0.013	
	95% CI	-0.046, 0.020	
	p-value	0.4521	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.6
Adverse Events of CTCAE Grade >=3 (disease-related AEs are excluded)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	21 (4.0)	12 (4.5)
	Unstratified Analysis		
	Odds Ratio	0.882	
	95% CI	0.427, 1.822	
	p-value	0.7344	
	Relative Risk	0.887	
	95% CI	0.443, 1.774	
	p-value	0.7342	
	Risk Difference	-0.005	
	95% CI	-0.035, 0.025	
	p-value	0.7390	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
Analysis excluded disease-related events assigned to Preferred Term Dermatitis atopic.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.7
Adverse Events of CTCAE Grade <3
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	350 (67.2)	167 (63.3)
	Unstratified Analysis		
	Odds Ratio	1.189	
	95% CI	0.872, 1.621	
	p-value	0.2739	
	Relative Risk	1.062	
	95% CI	0.952, 1.185	
	p-value	0.2830	
	Risk Difference	0.039	
	95% CI	-0.032, 0.110	
	p-value	0.2775	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.8
Adverse Events leading to discontinuation of study drug
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	7 (1.3)	6 (2.3)
	Unstratified Analysis		
	Odds Ratio	0.586	
	95% CI	0.195, 1.760	
	p-value	0.3406	
	Relative Risk	0.591	
	95% CI	0.201, 1.741	
	p-value	0.3403	
	Risk Difference	-0.009	
	95% CI	-0.030, 0.011	
	p-value	0.3747	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.9
Fatal Adverse Events
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.1
Adverse Events of Special Interest - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	3 (0.6)	3 (1.1)
	Unstratified Analysis		
	Odds Ratio	0.504	
	95% CI	0.101, 2.514	
	p-value	0.4032	
	Relative Risk	0.507	
	95% CI	0.103, 2.493	
	p-value	0.4031	
	Risk Difference	-0.006	
	95% CI	-0.020, 0.009	
	p-value	0.4436	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.2
Adverse Events of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	7 (1.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	7.711	
	95% CI	0.439, 135.537	
	p-value	0.1625	
	Relative Risk	7.615	
	95% CI	0.437, 132.821	
	p-value	0.1640	
	Risk Difference	0.013	
	95% CI	0.004, 0.023	
	p-value	0.0077	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.3
Adverse Events of Special Interest - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	7 (1.3)	3 (1.1)
	Unstratified Analysis		
	Odds Ratio	1.185	
	95% CI	0.304, 4.619	
	p-value	0.8070	
	Relative Risk	1.182	
	95% CI	0.308, 4.535	
	p-value	0.8071	
	Risk Difference	0.002	
	95% CI	-0.014, 0.018	
	p-value	0.8016	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.4
Adverse Events of Special Interest - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.5
Adverse Events of Special Interest - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	2 (0.4)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	2.546	
	95% CI	0.122, 53.217	
	p-value	0.5469	
	Relative Risk	2.538	
	95% CI	0.122, 52.681	
	p-value	0.5472	
	Risk Difference	0.004	
	95% CI	-0.001, 0.009	
	p-value	0.1565	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.6
Adverse Events of Special Interest - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	2 (0.4)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	2.546	
	95% CI	0.122, 53.217	
	p-value	0.5469	
	Relative Risk	2.538	
	95% CI	0.122, 52.681	
	p-value	0.5472	
	Risk Difference	0.004	
	95% CI	-0.001, 0.009	
	p-value	0.1565	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.7
Adverse Events of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.8
Adverse Events of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.9
Adverse Events of Special Interest - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.10
Adverse Events of Special Interest - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	7 (1.3)	5 (1.9)
	Unstratified Analysis		
	Odds Ratio	0.705	
	95% CI	0.222, 2.244	
	p-value	0.5546	
	Relative Risk	0.709	
	95% CI	0.227, 2.214	
	p-value	0.5543	
	Risk Difference	-0.006	
	95% CI	-0.025, 0.014	
	p-value	0.5740	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.11
Adverse Events of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.12
Adverse Events of Special Interest - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	3 (0.6)	1 (0.4)
	Unstratified Analysis		
	Odds Ratio	1.523	
	95% CI	0.158, 14.714	
	p-value	0.7161	
	Relative Risk	1.520	
	95% CI	0.159, 14.543	
	p-value	0.7162	
	Risk Difference	0.002	
	95% CI	-0.008, 0.012	
	p-value	0.6952	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.13
Adverse Events of Special Interest - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	4 (0.8)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	4.600	
	95% CI	0.247, 85.760	
	p-value	0.3066	
	Relative Risk	4.569	
	95% CI	0.247, 84.545	
	p-value	0.3075	
	Risk Difference	0.008	
	95% CI	0.000, 0.015	
	p-value	0.0447	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.14
Adverse Events of Special Interest - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
	Unstratified Analysis		
	Odds Ratio	0.168	
	95% CI	0.007, 4.149	
	p-value	0.2759	
	Relative Risk	0.169	
	95% CI	0.007, 4.140	
	p-value	0.2761	
	Risk Difference	-0.004	
	95% CI	-0.011, 0.004	
	p-value	0.3164	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.15
Adverse Events of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	28 (5.4)	7 (2.7)
	Unstratified Analysis		
	Odds Ratio	2.085	
	95% CI	0.899, 4.839	
	p-value	0.0871	
	Relative Risk	2.027	
	95% CI	0.897, 4.579	
	p-value	0.0893	
	Risk Difference	0.027	
	95% CI	-0.000, 0.055	
	p-value	0.0514	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.16
Adverse Events of Special Interest - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.17
Adverse Events of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.10.18
Adverse Events of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
	Unstratified Analysis		
	Odds Ratio	0.168	
	95% CI	0.007, 4.149	
	p-value	0.2759	
	Relative Risk	0.169	
	95% CI	0.007, 4.140	
	p-value	0.2761	
	Risk Difference	-0.004	
	95% CI	-0.011, 0.004	
	p-value	0.3164	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.1
Serious Adverse Events of Special Interest - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	3 (0.6)	3 (1.1)
	Unstratified Analysis		
	Odds Ratio	0.504	
	95% CI	0.101, 2.514	
	p-value	0.4032	
	Relative Risk	0.507	
	95% CI	0.103, 2.493	
	p-value	0.4031	
	Risk Difference	-0.006	
	95% CI	-0.020, 0.009	
	p-value	0.4436	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.2
Serious Adverse Events of Special Interest - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.3
Serious Adverse Events of Special Interest - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.4
Serious Adverse Events of Special Interest - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.5
Serious Adverse Events of Special Interest - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.6
Serious Adverse Events of Special Interest - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.7
Serious Adverse Events of Special Interest - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.8
Serious Adverse Events of Special Interest - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.9
Serious Adverse Events of Special Interest - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.10
Serious Adverse Events of Special Interest - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.11
Serious Adverse Events of Special Interest - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.12
Serious Adverse Events of Special Interest - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.13
Serious Adverse Events of Special Interest - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.14
Serious Adverse Events of Special Interest - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.15
Serious Adverse Events of Special Interest - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.16
Serious Adverse Events of Special Interest - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.17
Serious Adverse Events of Special Interest - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.11.18
Serious Adverse Events of Special Interest - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
	Unstratified Analysis		
	Odds Ratio	0.168	
	95% CI	0.007, 4.149	
	p-value	0.2759	
	Relative Risk	0.169	
	95% CI	0.007, 4.140	
	p-value	0.2761	
	Risk Difference	-0.004	
	95% CI	-0.011, 0.004	
	p-value	0.3164	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.1
Adverse Events of Special Interest of CTCAE Grade >=3 - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	3 (0.6)	3 (1.1)
	Unstratified Analysis		
	Odds Ratio	0.504	
	95% CI	0.101, 2.514	
	p-value	0.4032	
	Relative Risk	0.507	
	95% CI	0.103, 2.493	
	p-value	0.4031	
	Risk Difference	-0.006	
	95% CI	-0.020, 0.009	
	p-value	0.4436	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.2
Adverse Events of Special Interest of CTCAE Grade >=3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.3
Adverse Events of Special Interest of CTCAE Grade >=3 - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.4
Adverse Events of Special Interest of CTCAE Grade >=3 - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.5
Adverse Events of Special Interest of CTCAE Grade >=3 - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.6
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.7
Adverse Events of Special Interest of CTCAE Grade >=3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.8
Adverse Events of Special Interest of CTCAE Grade >=3 - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.9
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.10
Adverse Events of Special Interest of CTCAE Grade >=3 - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
	Unstratified Analysis		
	Odds Ratio	0.168	
	95% CI	0.007, 4.149	
	p-value	0.2759	
	Relative Risk	0.169	
	95% CI	0.007, 4.140	
	p-value	0.2761	
	Risk Difference	-0.004	
	95% CI	-0.011, 0.004	
	p-value	0.3164	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.11
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.12
Adverse Events of Special Interest of CTCAE Grade >=3 - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.13
Adverse Events of Special Interest of CTCAE Grade >=3 - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.14
Adverse Events of Special Interest of CTCAE Grade >=3 - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.15
Adverse Events of Special Interest of CTCAE Grade >=3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	2 (0.4)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	2.546	
	95% CI	0.122, 53.217	
	p-value	0.5469	
	Relative Risk	2.538	
	95% CI	0.122, 52.681	
	p-value	0.5472	
	Risk Difference	0.004	
	95% CI	-0.001, 0.009	
	p-value	0.1565	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.16
Adverse Events of Special Interest of CTCAE Grade >=3 - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.17
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.12.18
Adverse Events of Special Interest of CTCAE Grade >=3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
	Unstratified Analysis		
	Odds Ratio	0.168	
	95% CI	0.007, 4.149	
	p-value	0.2759	
	Relative Risk	0.169	
	95% CI	0.007, 4.140	
	p-value	0.2761	
	Risk Difference	-0.004	
	95% CI	-0.011, 0.004	
	p-value	0.3164	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.1
Adverse Events of Special Interest of CTCAE Grade <3 - Serious Infection
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
	Unstratified Analysis		
	Odds Ratio	0.168	
	95% CI	0.007, 4.149	
	p-value	0.2759	
	Relative Risk	0.169	
	95% CI	0.007, 4.140	
	p-value	0.2761	
	Risk Difference	-0.004	
	95% CI	-0.011, 0.004	
	p-value	0.3164	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.2
Adverse Events of Special Interest of CTCAE Grade <3 - Opportunistic infection excluding tuberculosis and herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	7 (1.3)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	7.711	
	95% CI	0.439, 135.537	
	p-value	0.1625	
	Relative Risk	7.615	
	95% CI	0.437, 132.821	
	p-value	0.1640	
	Risk Difference	0.013	
	95% CI	0.004, 0.023	
	p-value	0.0077	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.3
Adverse Events of Special Interest of CTCAE Grade <3 - Herpes zoster
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	6 (1.2)	3 (1.1)
	Unstratified Analysis		
	Odds Ratio	1.014	
	95% CI	0.251, 4.085	
	p-value	0.9849	
	Relative Risk	1.013	
	95% CI	0.255, 4.020	
	p-value	0.9849	
	Risk Difference	0.000	
	95% CI	-0.016, 0.016	
	p-value	0.9848	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.4
Adverse Events of Special Interest of CTCAE Grade <3 - Active tuberculosis
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.5
Adverse Events of Special Interest of CTCAE Grade <3 - Possible malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.6
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.7
Adverse Events of Special Interest of CTCAE Grade <3 - Non-melanoma skin cancer (NMSC)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.8
Adverse Events of Special Interest of CTCAE Grade <3 - Malignancy other than NMSC
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.9
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphoma
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.10
Adverse Events of Special Interest of CTCAE Grade <3 - Hepatic disorder
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	7 (1.3)	5 (1.9)
	Unstratified Analysis		
	Odds Ratio	0.705	
	95% CI	0.222, 2.244	
	p-value	0.5546	
	Relative Risk	0.709	
	95% CI	0.227, 2.214	
	p-value	0.5543	
	Risk Difference	-0.006	
	95% CI	-0.025, 0.014	
	p-value	0.5740	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.11
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated gastrointestinal perforation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.12
Adverse Events of Special Interest of CTCAE Grade <3 - Anemia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	2 (0.4)	1 (0.4)
	Unstratified Analysis		
	Odds Ratio	1.013	
	95% CI	0.091, 11.228	
	p-value	0.9913	
	Relative Risk	1.013	
	95% CI	0.092, 11.125	
	p-value	0.9913	
	Risk Difference	0.000	
	95% CI	-0.009, 0.009	
	p-value	0.9913	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.13
Adverse Events of Special Interest of CTCAE Grade <3 - Neutropenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	4 (0.8)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	4.600	
	95% CI	0.247, 85.760	
	p-value	0.3066	
	Relative Risk	4.569	
	95% CI	0.247, 84.545	
	p-value	0.3075	
	Risk Difference	0.008	
	95% CI	0.000, 0.015	
	p-value	0.0447	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.14
Adverse Events of Special Interest of CTCAE Grade <3 - Lymphopenia
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
	Unstratified Analysis		
	Odds Ratio	0.168	
	95% CI	0.007, 4.149	
	p-value	0.2759	
	Relative Risk	0.169	
	95% CI	0.007, 4.140	
	p-value	0.2761	
	Risk Difference	-0.004	
	95% CI	-0.011, 0.004	
	p-value	0.3164	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.15
Adverse Events of Special Interest of CTCAE Grade <3 - Creatine phosphokinase (CPK) elevation
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	26 (5.0)	7 (2.7)
	Unstratified Analysis		
	Odds Ratio	1.928	
	95% CI	0.826, 4.503	
	p-value	0.1291	
	Relative Risk	1.882	
	95% CI	0.828, 4.279	
	p-value	0.1313	
	Risk Difference	0.023	
	95% CI	-0.004, 0.050	
	p-value	0.0887	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.16
Adverse Events of Special Interest of CTCAE Grade <3 - Renal dysfunction
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	1.524	
	95% CI	0.062, 37.551	
	p-value	0.7965	
	Relative Risk	1.523	
	95% CI	0.062, 37.258	
	p-value	0.7965	
	Risk Difference	0.002	
	95% CI	-0.002, 0.006	
	p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.17
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated major adverse cardiovascular events (MACE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.1.13.18
Adverse Events of Special Interest of CTCAE Grade <3 - Adjudicated venous thromboembolic events (VTE)
(Safety Analysis Set)

Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
Week 16	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Unstratified Analysis		
	Odds Ratio	NE	
	95% CI	NE, NE	
	p-value	NE	
	Relative Risk	NE	
	95% CI	NE, NE	
	p-value	NE	
	Risk Difference	NE	
	95% CI	NE, NE	
	p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.2.1
Incidence of Adverse Events leading to discontinuation of study drug by SOC and PT
(Safety Analysis Set)

Up to Visit	System Organ Class (SOC) Preferred Term (PT)	Upadacitinib + TCS (N=521) n (%)	Placebo + TCS (N=264) n (%)
Week 16	Skin and subcutaneous tissue disorders	2 (0.4)	2 (0.8)
	Dermatitis atopic	2 (0.4)	1 (0.4)
	Dermatitis exfoliative generalised	0 (0.0)	1 (0.4)
	Infections and infestations	1 (0.2)	2 (0.8)
	Endocarditis	0 (0.0)	1 (0.4)
	Herpes ophthalmic	1 (0.2)	0 (0.0)
	Pneumonia	0 (0.0)	1 (0.4)
	Staphylococcal sepsis	0 (0.0)	1 (0.4)
	Investigations	0 (0.0)	2 (0.8)
	Blood creatine phosphokinase increased	0 (0.0)	1 (0.4)
	Weight increased	0 (0.0)	1 (0.4)
	Blood and lymphatic system disorders	1 (0.2)	0 (0.0)
	Neutropenia	1 (0.2)	0 (0.0)
	Gastrointestinal disorders	1 (0.2)	0 (0.0)
	Abdominal pain upper	1 (0.2)	0 (0.0)
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.2)	0 (0.0)
	Adenocarcinoma of colon	1 (0.2)	0 (0.0)
	Psychiatric disorders	1 (0.2)	0 (0.0)
	Mixed anxiety and depressive disorder	1 (0.2)	0 (0.0)
	Respiratory, thoracic and mediastinal disorders	0 (0.0)	1 (0.4)
	Acute respiratory failure	0 (0.0)	1 (0.4)

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.1 coding dictionary applied.
N: Number of subjects, n: Number of subjects with event
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Blood and lymphatic system disorders	Week 16	Number of subjects with events, n (%)	11 (2.1)	4 (1.5)
		Unstratified Analysis		
		Odds Ratio	1.402	
		95% CI	0.442, 4.446	
		p-value	0.5661	
		Relative Risk	1.393	
		95% CI	0.448, 4.334	
		p-value	0.5666	
		Risk Difference	0.006	
		95% CI	-0.013, 0.02	
		p-value	0.5433	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Eye disorders	Week 16	Number of subjects with events, n (%)	21 (4.0)	8 (3.0)
		Unstratified Analysis		
		Odds Ratio	1.344	
		95% CI	0.587, 3.076	
		p-value	0.4841	
		Relative Risk	1.330	
		95% CI	0.597, 2.962	
		p-value	0.4850	
		Risk Difference	0.010	
		95% CI	-0.017, 0.03	
		p-value	0.4627	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Gastrointestinal disorders	Week 16	Number of subjects with events, n (%)	76 (14.6)	20 (7.6)
		Unstratified Analysis		
		Odds Ratio	2.084	
		95% CI	1.243, 3.493	
		p-value	0.0054	
		Relative Risk	1.926	
		95% CI	1.204, 3.080	
		p-value	0.0063	
		Risk Difference	0.070	
		95% CI	0.026, 0.114	
		p-value	0.0018	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Gastrointestinal disorders - PT:Abdominal pain upper	Week 16	Number of subjects with events, n (%)	11 (2.1)	1 (0.4)
		Unstratified Analysis		
		Odds Ratio	5.673	
		95% CI	0.728, 44.175	
		p-value	0.0974	
		Relative Risk	5.574	
		95% CI	0.723, 42.942	
		p-value	0.0991	
		Risk Difference	0.017	
		95% CI	0.003, 0.032	
		p-value	0.0183	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Gastrointestinal disorders - PT:Diarrhoea	Week 16	Number of subjects with events, n (%)	19 (3.6)	4 (1.5)
		Unstratified Analysis		
		Odds Ratio	2.460	
		95% CI	0.828, 7.307	
		p-value	0.1050	
		Relative Risk	2.407	
		95% CI	0.827, 7.003	
		p-value	0.1070	
		Risk Difference	0.021	
		95% CI	-0.001, 0.04	
		p-value	0.0555	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Gastrointestinal disorders - PT:Nausea	Week 16	Number of subjects with events, n (%)	12 (2.3)	0 (0.0)
		Unstratified Analysis		
		Odds Ratio	12.978	
		95% CI	0.765, 220.057	
		p-value	0.0759	
		Relative Risk	12.692	
		95% CI	0.754, 213.528	
		p-value	0.0777	
		Risk Difference	0.023	
		95% CI	0.010, 0.036	
		p-value	0.0005	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: General disorders and administration site conditions	Week 16	Number of subjects with events, n (%)	38 (7.3)	13 (4.9)
		Unstratified Analysis		
		Odds Ratio	1.519	
		95% CI	0.795, 2.904	
		p-value	0.2060	
		Relative Risk	1.481	
		95% CI	0.803, 2.732	
		p-value	0.2084	
		Risk Difference	0.024	
		95% CI	-0.011, 0.05	
		p-value	0.1764	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Infections and infestations	Week 16	Number of subjects with events, n (%)	229 (44.0)	102 (38.6)
		Unstratified Analysis		
		Odds Ratio	1.246	
		95% CI	0.921, 1.685	
		p-value	0.1543	
		Relative Risk	1.138	
		95% CI	0.950, 1.362	
		p-value	0.1610	
		Risk Difference	0.053	
		95% CI	-0.019, 0.12	
		p-value	0.1509	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Infections and infestations - PT:Folliculitis	Week 16	Number of subjects with events, n (%)	17 (3.3)	3 (1.1)
		Unstratified Analysis		
		Odds Ratio	2.935	
		95% CI	0.852, 10.105	
		p-value	0.0879	
		Relative Risk	2.871	
		95% CI	0.849, 9.711	
		p-value	0.0897	
		Risk Difference	0.021	
		95% CI	0.001, 0.041	
		p-value	0.0363	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Infections and infestations - PT:Herpes simplex	Week 16	Number of subjects with events, n (%)	11 (2.1)	1 (0.4)
		Unstratified Analysis		
		Odds Ratio	5.673	
		95% CI	0.728, 44.175	
		p-value	0.0974	
		Relative Risk	5.574	
		95% CI	0.723, 42.942	
		p-value	0.0991	
		Risk Difference	0.017	
		95% CI	0.003, 0.032	
		p-value	0.0183	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Infections and infestations - PT:Influenza	Week 16	Number of subjects with events, n (%)	15 (2.9)	2 (0.8)
		Unstratified Analysis		
		Odds Ratio	3.883	
		95% CI	0.881, 17.110	
		p-value	0.0730	
		Relative Risk	3.800	
		95% CI	0.876, 16.495	
		p-value	0.0747	
		Risk Difference	0.021	
		95% CI	0.003, 0.039	
		p-value	0.0192	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Infections and infestations - PT:Nasopharyngitis	Week 16	Number of subjects with events, n (%)	68 (13.1)	31 (11.7)
		Unstratified Analysis		
		Odds Ratio	1.128	
		95% CI	0.717, 1.775	
		p-value	0.6018	
		Relative Risk	1.112	
		95% CI	0.746, 1.655	
		p-value	0.6027	
		Risk Difference	0.013	
		95% CI	-0.035, 0.06	
		p-value	0.5961	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Infections and infestations - PT:Oral herpes	Week 16	Number of subjects with events, n (%)	31 (6.0)	5 (1.9)
		Unstratified Analysis		
		Odds Ratio	3.277	
		95% CI	1.259, 8.529	
		p-value	0.0150	
		Relative Risk	3.142	
		95% CI	1.236, 7.986	
		p-value	0.0162	
		Risk Difference	0.041	
		95% CI	0.014, 0.067	
		p-value	0.0024	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Infections and infestations - PT:Upper respiratory tract infection	Week 16	Number of subjects with events, n (%)	39 (7.5)	21 (8.0)
		Unstratified Analysis		
		Odds Ratio	0.936	
		95% CI	0.539, 1.627	
		p-value	0.8153	
		Relative Risk	0.941	
		95% CI	0.565, 1.566	
		p-value	0.8152	
		Risk Difference	-0.005	
		95% CI	-0.044, 0.03	
		p-value	0.8169	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Infections and infestations - PT:Urinary tract infection	Week 16	Number of subjects with events, n (%)	15 (2.9)	6 (2.3)
		Unstratified Analysis		
		Odds Ratio	1.275	
		95% CI	0.489, 3.324	
		p-value	0.6197	
		Relative Risk	1.267	
		95% CI	0.497, 3.227	
		p-value	0.6201	
		Risk Difference	0.006	
		95% CI	-0.017, 0.02	
		p-value	0.6055	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Injury, poisoning and procedural complications	Week 16	Number of subjects with events, n (%)	28 (5.4)	9 (3.4)
		Unstratified Analysis		
		Odds Ratio	1.609	
		95% CI	0.748, 3.462	
		p-value	0.2236	
		Relative Risk	1.576	
		95% CI	0.755, 3.292	
		p-value	0.2256	
		Risk Difference	0.020	
		95% CI	-0.010, 0.04	
		p-value	0.1875	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Investigations	Week 16	Number of subjects with events, n (%)	48 (9.2)	23 (8.7)
		Unstratified Analysis		
		Odds Ratio	1.063	
		95% CI	0.632, 1.790	
		p-value	0.8172	
		Relative Risk	1.057	
		95% CI	0.658, 1.700	
		p-value	0.8174	
		Risk Difference	0.005	
		95% CI	-0.037, 0.04	
		p-value	0.8157	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Investigations - PT:Blood creatine phosphokinase increased	Week 16	Number of subjects with events, n (%)	28 (5.4)	7 (2.7)
		Unstratified Analysis		
		Odds Ratio	2.085	
		95% CI	0.899, 4.839	
		p-value	0.0871	
		Relative Risk	2.027	
		95% CI	0.897, 4.579	
		p-value	0.0893	
		Risk Difference	0.027	
		95% CI	-0.000, 0.05	
		p-value	0.0514	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Metabolism and nutrition disorders	Week 16	Number of subjects with events, n (%)	11 (2.1)	7 (2.7)
		Unstratified Analysis		
		Odds Ratio	0.792	
		95% CI	0.303, 2.067	
		p-value	0.6336	
		Relative Risk	0.796	
		95% CI	0.312, 2.030	
		p-value	0.6333	
		Risk Difference	-0.005	
		95% CI	-0.028, 0.01	
		p-value	0.6450	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Musculoskeletal and connective tissue disorders	Week 16	Number of subjects with events, n (%)	36 (6.9)	11 (4.2)
		Unstratified Analysis		
		Odds Ratio	1.707	
		95% CI	0.854, 3.411	
		p-value	0.1299	
		Relative Risk	1.658	
		95% CI	0.858, 3.205	
		p-value	0.1324	
		Risk Difference	0.027	
		95% CI	-0.005, 0.06	
		p-value	0.0979	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Nervous system disorders	Week 16	Number of subjects with events, n (%)	38 (7.3)	17 (6.4)
		Unstratified Analysis		
		Odds Ratio	1.143	
		95% CI	0.632, 2.066	
		p-value	0.6580	
		Relative Risk	1.133	
		95% CI	0.652, 1.968	
		p-value	0.6585	
		Risk Difference	0.009	
		95% CI	-0.029, 0.04	
		p-value	0.6516	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Nervous system disorders - PT:Headache	Week 16	Number of subjects with events, n (%)	22 (4.2)	12 (4.5)
		Unstratified Analysis		
		Odds Ratio	0.926	
		95% CI	0.451, 1.901	
		p-value	0.8338	
		Relative Risk	0.929	
		95% CI	0.467, 1.848	
		p-value	0.8337	
		Risk Difference	-0.003	
		95% CI	-0.034, 0.02	
		p-value	0.8356	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Psychiatric disorders	Week 16	Number of subjects with events, n (%)	19 (3.6)	4 (1.5)
		Unstratified Analysis		
		Odds Ratio	2.460	
		95% CI	0.828, 7.307	
		p-value	0.1050	
		Relative Risk	2.407	
		95% CI	0.827, 7.003	
		p-value	0.1070	
		Risk Difference	0.021	
		95% CI	-0.001, 0.04	
		p-value	0.0555	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Reproductive system and breast disorders	Week 16	Number of subjects with events, n (%)	16 (3.1)	3 (1.1)
		Unstratified Analysis		
		Odds Ratio	2.756	
		95% CI	0.796, 9.546	
		p-value	0.1096	
		Relative Risk	2.702	
		95% CI	0.795, 9.192	
		p-value	0.1115	
		Risk Difference	0.019	
		95% CI	-0.000, 0.03	
		p-value	0.0527	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Respiratory, thoracic and mediastinal disorders	Week 16	Number of subjects with events, n (%)	55 (10.6)	19 (7.2)
		Unstratified Analysis		
		Odds Ratio	1.522	
		95% CI	0.883, 2.622	
		p-value	0.1303	
		Relative Risk	1.467	
		95% CI	0.890, 2.419	
		p-value	0.1333	
		Risk Difference	0.034	
		95% CI	-0.007, 0.07	
		p-value	0.1069	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Respiratory, thoracic and mediastinal disorders - PT:Cough	Week 16	Number of subjects with events, n (%)	20 (3.8)	4 (1.5)
		Unstratified Analysis		
		Odds Ratio	2.595	
		95% CI	0.878, 7.671	
		p-value	0.0847	
		Relative Risk	2.534	
		95% CI	0.875, 7.337	
		p-value	0.0866	
		Risk Difference	0.023	
		95% CI	0.001, 0.045	
		p-value	0.0395	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Respiratory, thoracic and mediastinal disorders - PT:Oropharyngeal pain	Week 16	Number of subjects with events, n (%)	13 (2.5)	3 (1.1)
		Unstratified Analysis		
		Odds Ratio	2.226	
		95% CI	0.629, 7.882	
		p-value	0.2147	
		Relative Risk	2.196	
		95% CI	0.631, 7.638	
		p-value	0.2162	
		Risk Difference	0.014	
		95% CI	-0.005, 0.03	
		p-value	0.1503	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Skin and subcutaneous tissue disorders	Week 16	Number of subjects with events, n (%)	120 (23.0)	37 (14.0)
		Unstratified Analysis		
		Odds Ratio	1.836	
		95% CI	1.227, 2.747	
		p-value	0.0031	
		Relative Risk	1.643	
		95% CI	1.173, 2.303	
		p-value	0.0039	
		Risk Difference	0.090	
		95% CI	0.035, 0.145	
		p-value	0.0014	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Skin and subcutaneous tissue disorders - PT:Acne	Week 16	Number of subjects with events, n (%)	61 (11.7)	6 (2.3)
		Unstratified Analysis		
		Odds Ratio	5.702	
		95% CI	2.432, 13.372	
		p-value	<.0001	
		Relative Risk	5.152	
		95% CI	2.257, 11.760	
		p-value	<.0001	
		Risk Difference	0.094	
		95% CI	0.061, 0.127	
		p-value	<.0001	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Skin and subcutaneous tissue disorders - PT:Dermatitis atopic	Week 16	Number of subjects with events, n (%)	10 (1.9)	18 (6.8)
		Unstratified Analysis		
		Odds Ratio	0.267	
		95% CI	0.122, 0.588	
		p-value	0.0010	
		Relative Risk	0.282	
		95% CI	0.132, 0.601	
		p-value	0.0011	
		Risk Difference	-0.049	
		95% CI	-0.082, -0.01	
		p-value	0.0032	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.1
Frequent Adverse Events by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

SOC/PT	Up to Visit		Upadacitinib + TCS (N=521)	Placebo + TCS (N=264)
SOC: Vascular disorders	Week 16	Number of subjects with events, n (%)	10 (1.9)	5 (1.9)
		Unstratified Analysis		
		Odds Ratio	1.014	
		95% CI	0.343, 2.997	
		p-value	0.9804	
		Relative Risk	1.013	
		95% CI	0.350, 2.935	
		p-value	0.9804	
		Risk Difference	0.000	
		95% CI	-0.020, 0.02	
		p-value	0.9803	

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.2
Frequent Serious Adverse Events by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

!!! There are no Observations for this Report !!!

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.

Adults (>= 18 years of age at the time of the screening visit)
Table 3.3.3
Frequent Adverse Events of CTCAE Grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
(Safety Analysis Set)

!!! There are no Observations for this Report !!!

Analysis based on Treatment-Emergent Adverse Events (TEAEs). TEAEs are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in Blinded-Extension Period or no more than 30 days after the last dose of study drug in Double-Blind Period, whichever occurs first.
MedDRA v22.0 coding dictionary applied.
N: Number of subjects, CI: Confidence Interval, NE: Not estimable
Odds Ratio, Relative Risk, Risk Difference were constructed using proc freq. In case of zero frequencies 0.5 is added to every cell as correction.
95% CI for Odds Ratio, Relative Risk, Risk Difference were constructed using normal approximation (Wald). P-values for Odds Ratio, Relative Risk, Risk Difference were calculated using Wald test.
The Upadacitinib + TCS arm contains the Upadacitinib 15 mg and the Upadacitinib 30 mg treatment groups.