Modul 4B Anhang 4-G

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Elotuzumab (EMPLICITI®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4 B – Anhang 4-G

Ergänzende Analysen zu der Studie ELOQUENT-3 (Datenschnitt: 02/2021)

Stand: 30.06.2021

Inhaltsverzeichnis

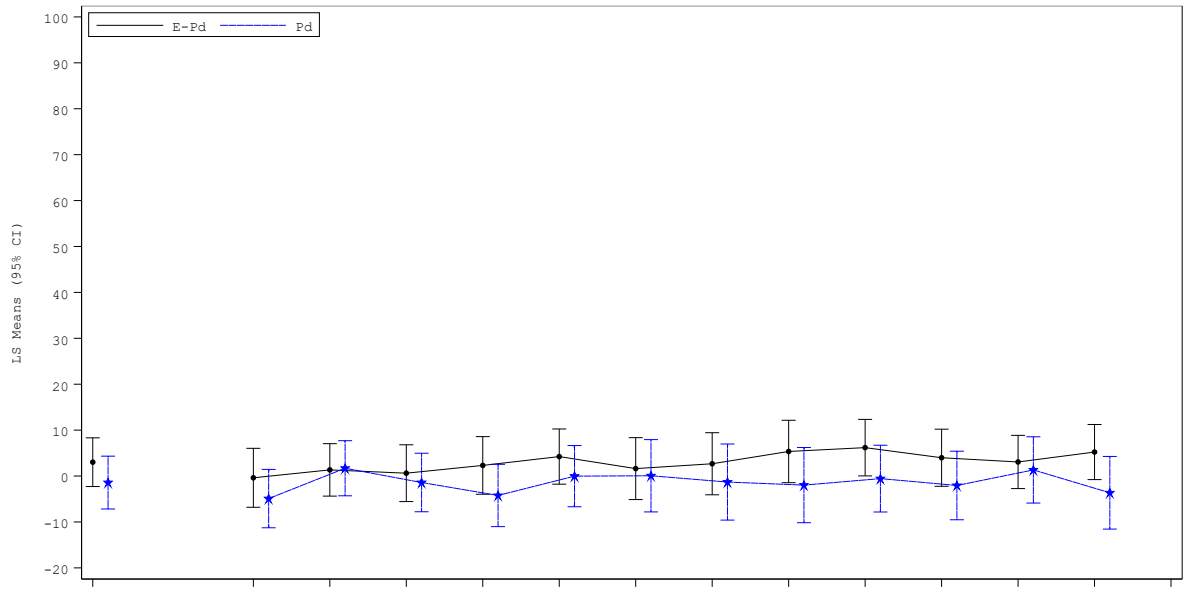
Anhang 4-G : Ergänzende Analysen 4
G.1 : Zeitlicher Verlauf des Gesundheitszustands gemessen anhand der EQ-5D VAS 4
G.2 : Ergänzende Auswertungen der Zeit bis zur Verschlechterung für den Endpunkt Gesundheitszustand gemessen anhand der EQ-5D VAS 5
Zeit bis zur ersten Verschlechterung und bis zur endgültigen Verschlechterung des Gesundheitszustands gemessen anhand der EQ-5D VAS um ≥ 15 Punkte (ITT-Population) 5
G.3 : Zeitlicher Verlauf des Gesundheitszustands gemessen anhand des MDASI-MM ... 6
Zeitlicher Verlauf des Gesundheitszustands gemessen anhand des MDASI-MM (Core Symptom Severity) 6
Zeitlicher Verlauf des Gesundheitszustands gemessen anhand des MDASI-MM (Module Symptom Severity) 7
Zeitlicher Verlauf des Gesundheitszustands gemessen anhand des MDASI-MM (Total Symptom Severity) 8
G.4 : Zeitlicher Verlauf der Lebensqualität gemessen anhand des MDASI-MM 9
Zeitlicher Verlauf der Lebensqualität gemessen anhand des MDASI-MM (Activity Interference) 9
Zeitlicher Verlauf der Lebensqualität gemessen anhand des MDASI-MM (Affective Interference) 10
Zeitlicher Verlauf der Lebensqualität gemessen anhand des MDASI-MM (Symptom Interference) 11
G.5 : Darstellung der Kaplan-Meier-Kurven für die Gesamtbetrachtung der UE ohne Progressterme 12
Kaplan-Meier-Kurve für jegliche UE (ohne Progressterme) 12
Kaplan-Meier-Kurve für schwere UE (CTCAE-Grad ≥ 3, ohne Progressterme) 12
Kaplan-Meier-Kurve für schwerwiegende UE (ohne Progressterme) 13
Kaplan-Meier-Kurve für zum Therapieabbruch führende UE (ohne Progressterme) 13
G.6 : Darstellung der Kaplan-Meier-Kurven für UE von besonderem Interesse 14
Kaplan-Meier-Kurve für jegliche UE von besonderem Interesse 14
Kaplan-Meier-Kurve für Infusionsreaktionen 14
Kaplan-Meier-Kurve für opportunistische Infektionen 15
Kaplan-Meier-Kurve für zweite Primärtumore 15
G.7 : Darstellung der Kaplan-Meier-Kurven für schwere UE (CTCAE-Grad ≥ 3) von besonderem Interesse 16
Kaplan-Meier-Kurve für schwere UE (CTCAE-Grad ≥ 3) von besonderem Interesse 16
Kaplan-Meier-Kurve für Infusionsreaktionen (CTCAE-Grad ≥ 3) 16
Kaplan-Meier-Kurve für opportunistische Infektionen (CTCAE-Grad ≥ 3) 17
G.8 : Darstellung der Kaplan-Meier-Kurven für schwerwiegende UE von besonderem Interesse 17
Kaplan-Meier-Kurve für schwerwiegende UE von besonderem Interesse 17
Kaplan-Meier-Kurve für schwerwiegende Infusionsreaktionen 18
Kaplan-Meier-Kurve für schwerwiegende opportunistische Infektionen 18
G.9 : Darstellung jeglicher UE, schwerer UE (CTCAE-Grad ≥ 3), SUE und zum Therapieabbruch führender UE auf SOC/PT-Ebene 19
G.10 : Darstellung aller Subgruppenanalysen 34
Subgruppenergebnisse für den Endpunkt Gesamtüberleben 34

Subgruppenergebnisse für den Endpunkt Gesundheitszustand gemessen anhand des EQ-5D VAS 45
Subgruppenergebnisse für den Endpunkt Gesundheitszustand gemessen anhand des MDASI-MM 51
Subgruppenergebnisse für den Endpunkt Gesundheitsbezogene Lebensqualität gemessen anhand des MDASI-MM 69
Subgruppenergebnisse für den Endpunkt Verträglichkeit (inkl. Subgruppenergebnisse auf SOC/PT-Ebene) 87

Anhang 4-G: Ergänzende Analysen

G.1: Zeitlicher Verlauf des Gesundheitszustands gemessen anhand der EQ-5D VAS

Figure 1.2.2: EQ-5D VAS: LS Mean Scores (95% CI) across Timepoint between E-Pd and Pd for the All Randomized Population [Feb 2021 DBL]



E-Pd (N=57)												
52	48	49	42	41	39	36	35	29	27	27	27	26	20
Pd (N=53)												
48	47	41	39	33	26	21	17	16	14	12	11	11	8

The All Randomized population was defined as all enrolled subjects who were randomized.

The EQ-5D VAS score ranges from 0-100 with higher scores associated with better health states.

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G.2: Ergänzende Auswertungen der Zeit bis zur Verschlechterung für den Endpunkt Gesundheitszustand gemessen anhand der EQ-5D VAS

Zeit bis zur ersten Verschlechterung und bis zur endgültigen Verschlechterung des Gesundheitszustands gemessen anhand der EQ-5D VAS um ≥ 15 Punkte (ITT-Population)

E-Pd (N = 60)			Pd (N = 57)			E-Pd vs. Pd	
Patienten mit Ereignis n/N (%)	**Zensierte Patienten n/N (%)**	**Median [95 %-KI] (Monate) [1]**	**Patienten mit Ereignis n/N (%)**	**Zensierte Patienten n/N (%)**	**Median [95 %-KI] (Monate) [1]**	**Hazard Ratio [95 %-KI] [2]**	**p-Wert [2]**
EQ-5D VAS - Zeit bis zur ersten Verschlechterung (MID 15 Punkte)							
29/60 (48,3)	31/60 (51,7)	6,51 [2,79; N.A.]	25/57 (43,9)	32/57 (56,1)	3,75 [1,91; N.A.]	0,953 [0,534; 1,700]	0,8705
EQ-5D VAS - Zeit bis zur endgültigen Verschlechterung (MID 15 Punkte)							
16/60 (26,7)	44/60 (73,3)	49,97 [25,63; N.A.]	19/57 (33,3)	38/57 (66,7)	32,39 [14,78; 47,08]	0,632 [0,301; 1,327]	0,2254

(1) Kaplan-Meier-Schätzer. Das 2-seitige 95 %-KI wurde nach Brookmeyer-Crowley berechnet (log-log Transformation).

(2) Cox-Modell stratifiziert nach Anzahl der vorangegangenen Therapielinien und Krankheitsstadium zu Studienbeginn.

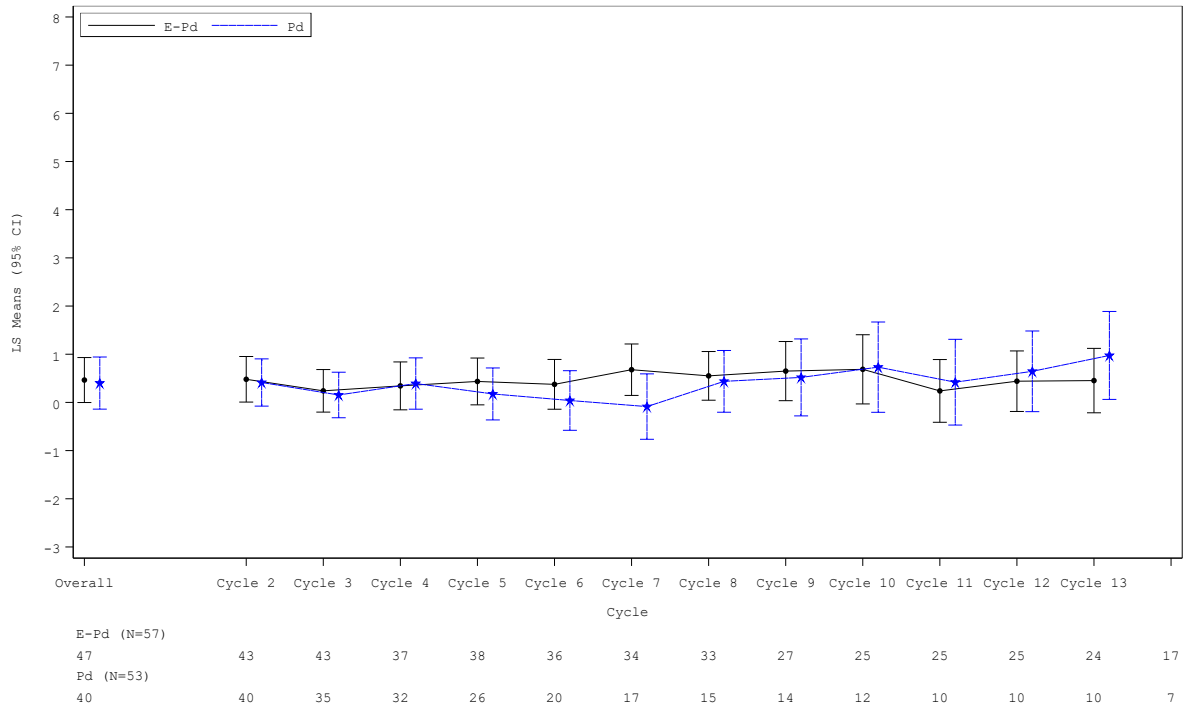
Datenschnitt: 02/2021

EQ-5D VAS: *European Quality of Life Questionnaire 5 Dimensions visual analog scale*; KI: Konfidenzintervall; p-Wert: p-Wert des log-rank Tests; MID: *minimal important difference*; NE: nicht berechenbar

G.3: Zeitlicher Verlauf des Gesundheitszustands gemessen anhand des MDASI-MM

Zeitlicher Verlauf des Gesundheitszustands gemessen anhand des MDASI-MM (Core Symptom Severity)

Figure 1.1.1: MDASI-MM: Core Symptom Severity: LS Mean Scores (95% CI) across Timepoint between E-Pd and Pd for the All Randomized Population [Feb 2021 DBL]



E-Pd (N=57)												
47	43	43	37	38	36	34	33	27	25	25	25	24	17
Pd (N=53)												
40	40	35	32	26	20	17	15	14	12	10	10	10	7

The All Randomized population was defined as all enrolled subjects who were randomized.

The MDASI-MM subscale and item scores range from 0 to 10 with higher scores meaning worse symptom severity.

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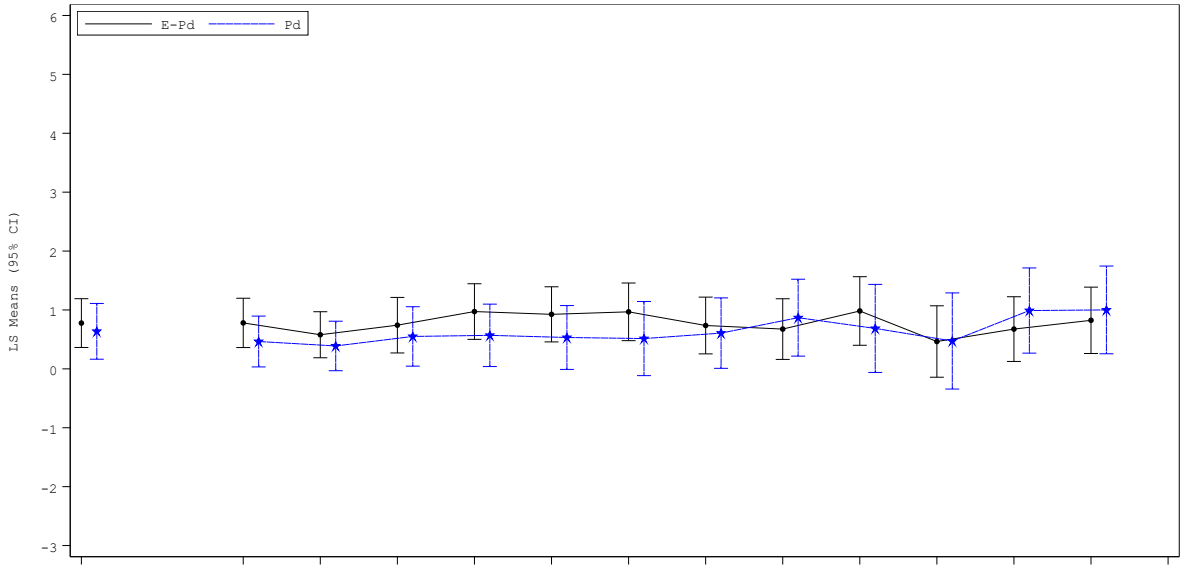
Zeitlicher Verlauf des Gesundheitszustands gemessen anhand des MDASI-MM (Module Symptom Severity)

Figure 1.1.2: MDASI-MM: Module Symptom Severity: LS Mean Scores (95% CI) across Timepoint between E-Pd and Pd for the All Randomized Population [Feb 2021 DBL]



E-Pd (N=57)												
46	42	43	37	38	36	34	33	26	25	25	25	24	17
Pd (N=53)												
40	40	35	32	26	20	17	15	13	12	10	10	10	7

The All Randomized population was defined as all enrolled subjects who were randomized.

The MDASI-MM subscale and item scores range from 0 to 10 with higher scores meaning worse symptom severity.

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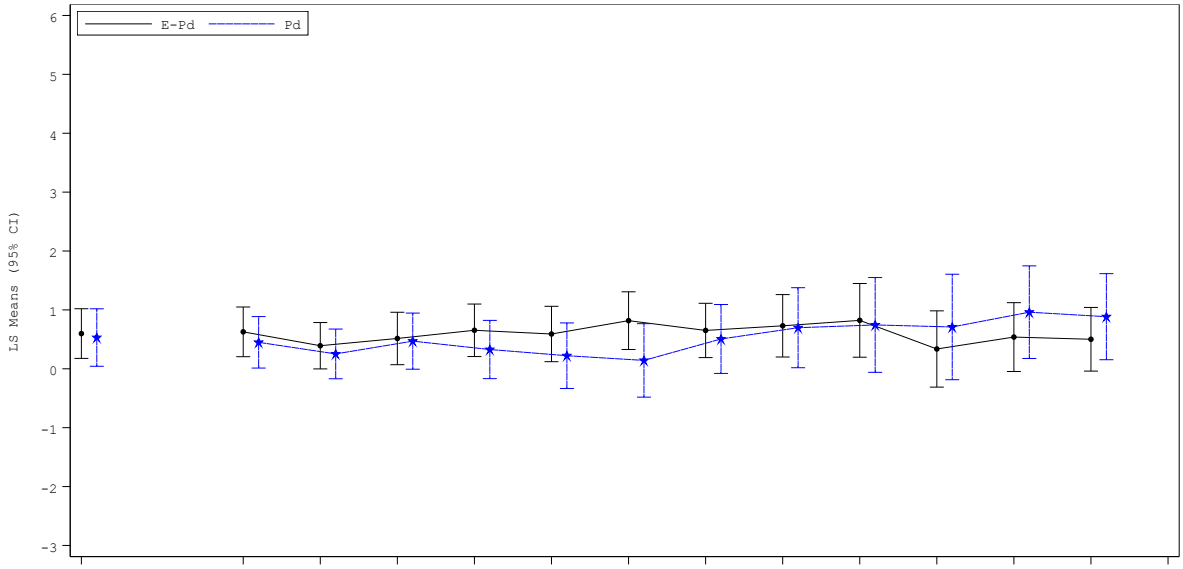
Zeitlicher Verlauf des Gesundheitszustands gemessen anhand des MDASI-MM (Total Symptom Severity)

Figure 1.1.3: MDASI-MM: Total Symptom Severity: LS Mean Scores (95% CI) across Timepoint between E-Pd and Pd for the All Randomized Population [Feb 2021 DBL]



E-Pd (N=57)												
47	43	43	37	38	36	34	33	27	25	25	25	24	17
Pd (N=53)												
40	40	35	32	26	20	17	15	14	12	10	10	10	7

The All Randomized population was defined as all enrolled subjects who were randomized.

The MDASI-MM subscale and item scores range from 0 to 10 with higher scores meaning worse symptom severity.

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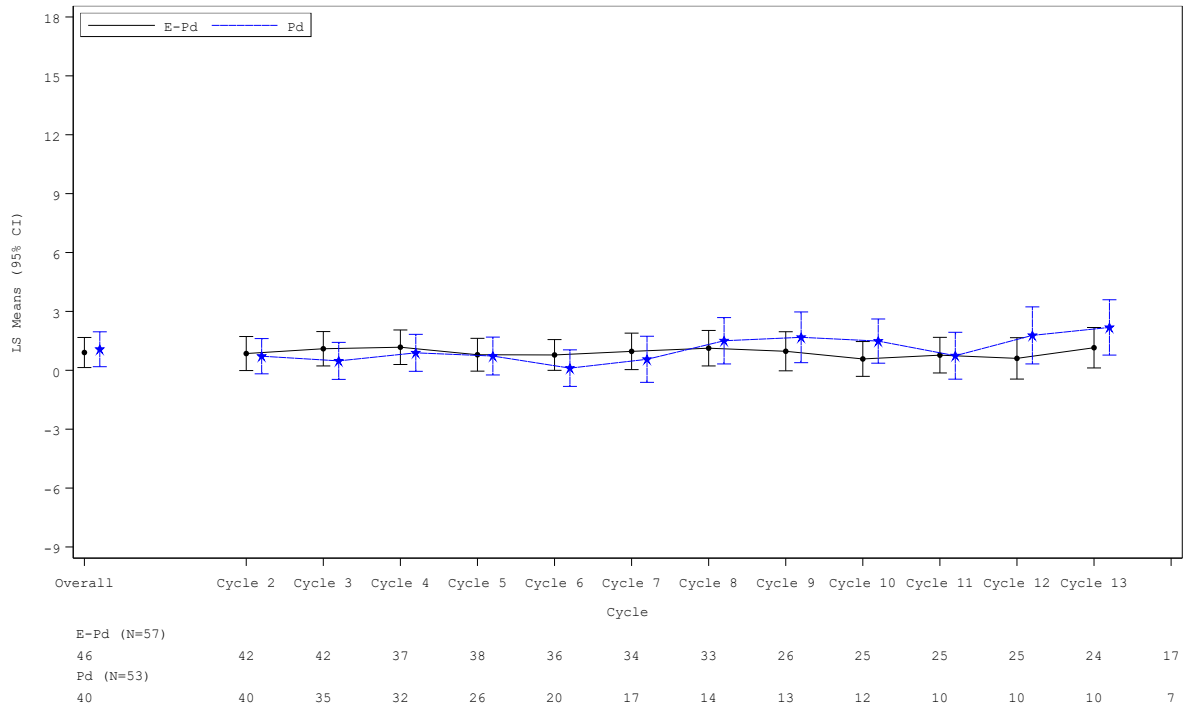
G.4: Zeitlicher Verlauf der Lebensqualität gemessen anhand des MDASI-MM

Zeitlicher Verlauf der Lebensqualität gemessen anhand des MDASI-MM (Activity Interference)

Figure 1.1.5: MDASI-MM: Activity Interference: LS Mean Scores (95% CI) across Timepoint between E-Pd and Pd for the All Randomized Population [Feb 2021 DBL]



E-Pd (N=57)													
46	42	42	37	38	36	34	33	26	25	25	25	24	17
Pd (N=53)													
40	40	35	32	26	20	17	14	13	12	10	10	10	7

The All Randomized population was defined as all enrolled subjects who were randomized.

The MDASI-MM subscale and item scores range from 0 to 10 with higher scores meaning worse symptom severity.

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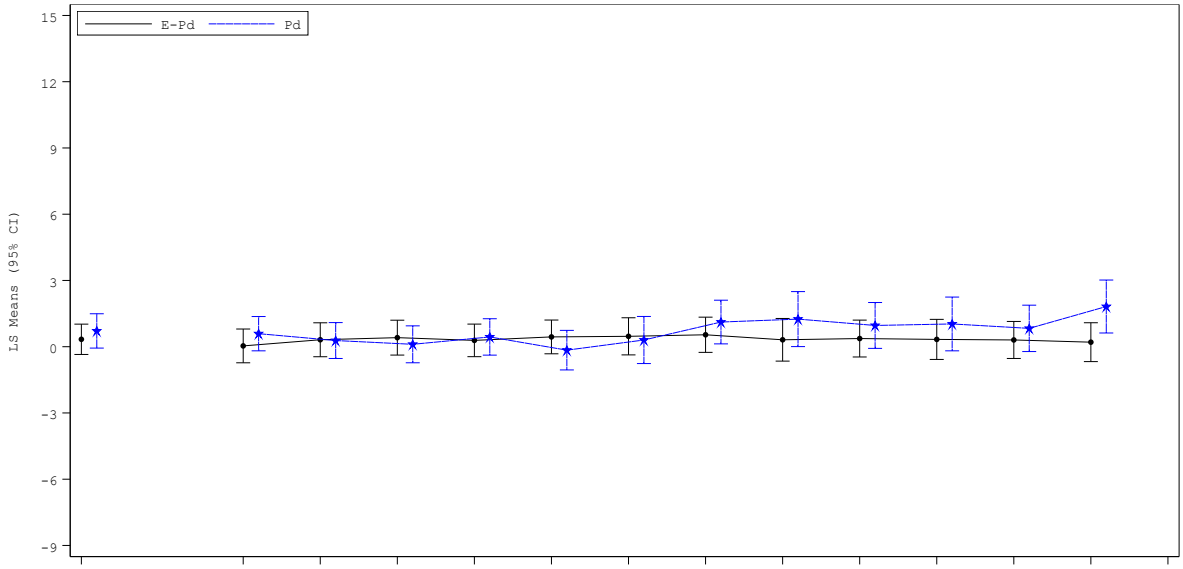
Zeitlicher Verlauf der Lebensqualität gemessen anhand des MDASI-MM (Affective Interference)

Figure 1.1.6: MDASI-MM: Affective Interference: LS Mean Scores (95% CI) across Timepoint between E-Pd and Pd for the All Randomized Population [Feb 2021 DBL]



E-Pd (N=57)												
46	42	42	37	38	36	34	33	26	25	25	25	24	17
Pd (N=53)												
40	40	35	32	26	20	17	14	13	12	10	10	10	7

The All Randomized population was defined as all enrolled subjects who were randomized.

The MDASI-MM subscale and item scores range from 0 to 10 with higher scores meaning worse symptom severity.

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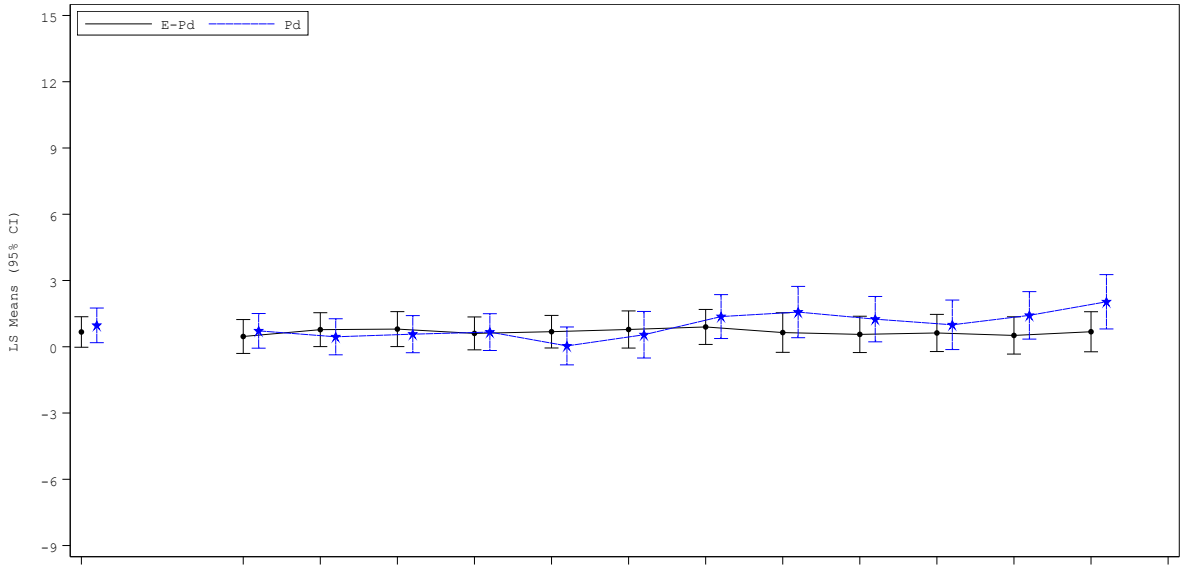
Zeitlicher Verlauf der Lebensqualität gemessen anhand des MDASI-MM (Symptom Interference)

Figure 1.1.4: MDASI-MM: Symptom Interference: LS Mean Scores (95% CI) across Timepoint between E-Pd and Pd for the All Randomized Population [Feb 2021 DBL]



E-Pd (N=57)													
46	42	42	37	38	36	34	33	26	25	25	25	24	17
Pd (N=53)													
40	40	35	32	26	20	17	14	13	12	10	10	10	7

The All Randomized population was defined as all enrolled subjects who were randomized.

The MDASI-MM subscale and item scores range from 0 to 10 with higher scores meaning worse symptom severity.

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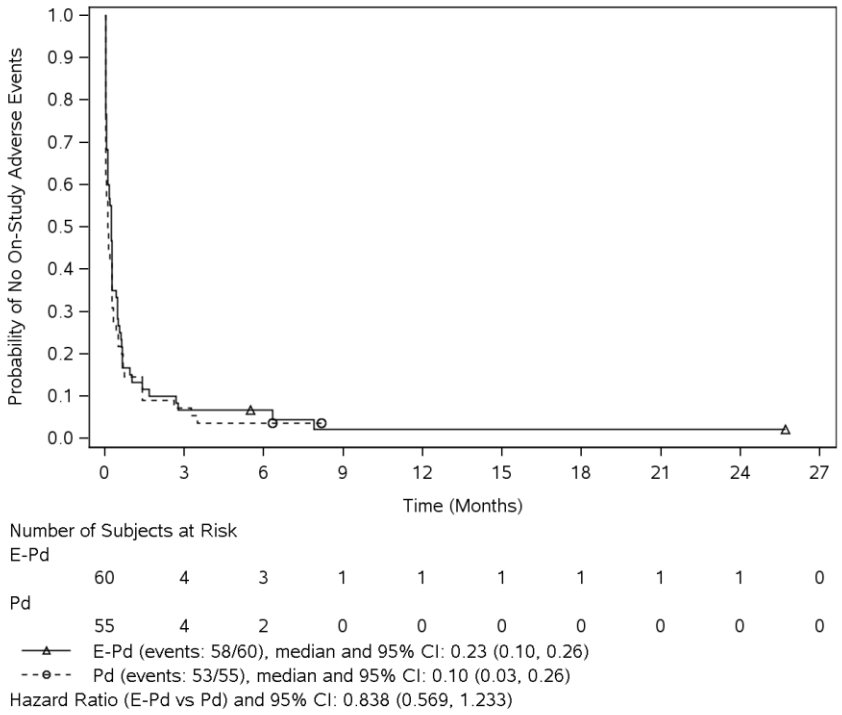
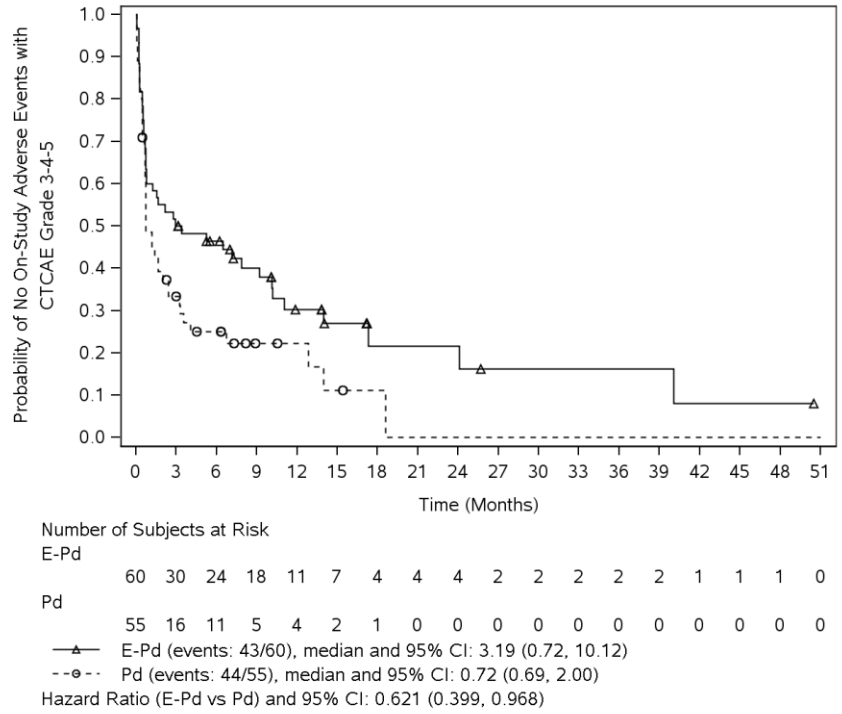
G.5: Darstellung der Kaplan-Meier-Kurven für die Gesamtbetrachtung der UE ohne Progressterme

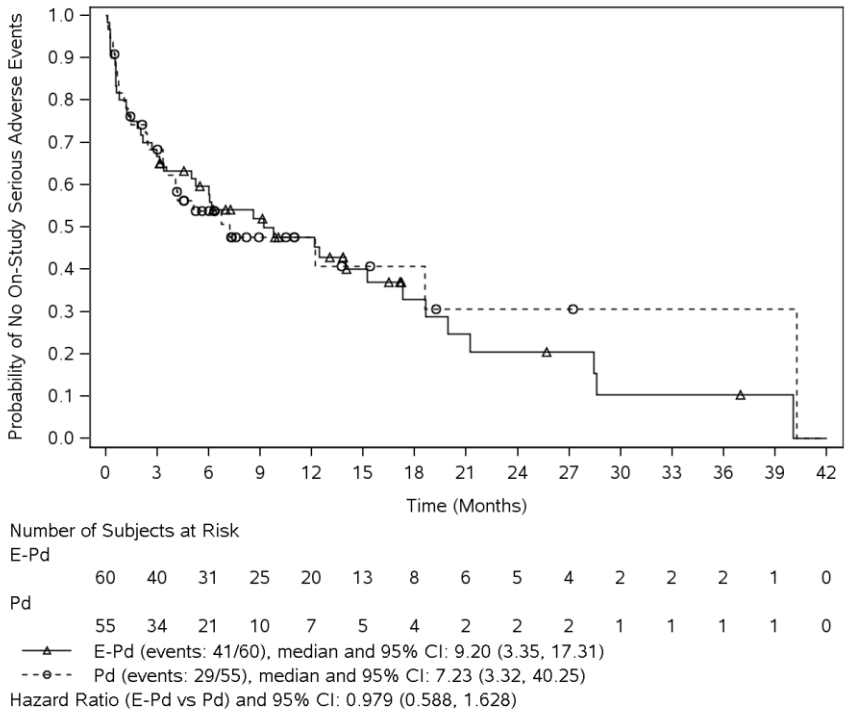
Kaplan-Meier-Kurve für jegliche UE (ohne Progressterme)



Kaplan-Meier-Kurve für schwere UE (CTCAE-Grad ≥ 3, ohne Progressterme)



Kaplan-Meier-Kurve für schwerwiegende UE (ohne Progressterme)

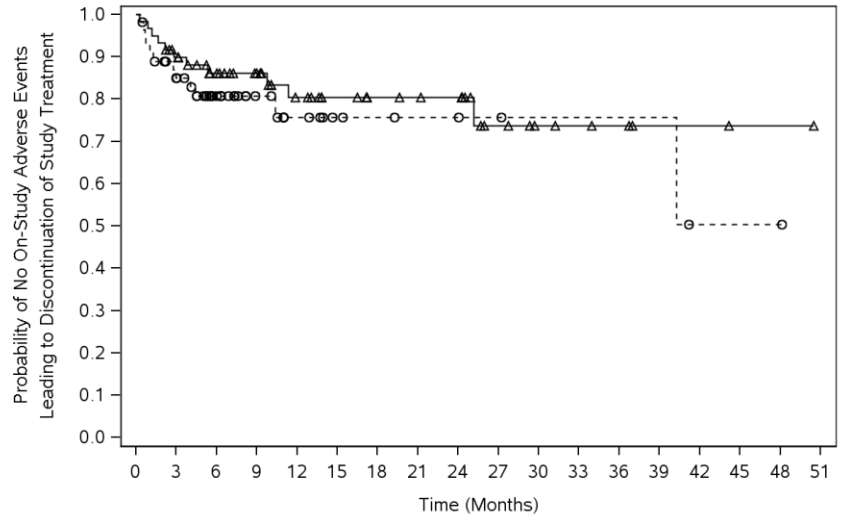


Number of Subjects at Risk

E-Pd	60	40	31	25	20	13	8	6	5	4	2	2	2	1	0
Pd	55	34	21	10	7	5	4	2	2	2	1	1	1	1	0

E-Pd (events: 41/60), median and 95% CI: 9.20 (3.35, 17.31)
Pd (events: 29/55), median and 95% CI: 7.23 (3.32, 40.25)
Hazard Ratio (E-Pd vs Pd) and 95% CI: 0.979 (0.588, 1.628)

Kaplan-Meier-Kurve für zum Therapieabbruch führende UE (ohne Progressterme)



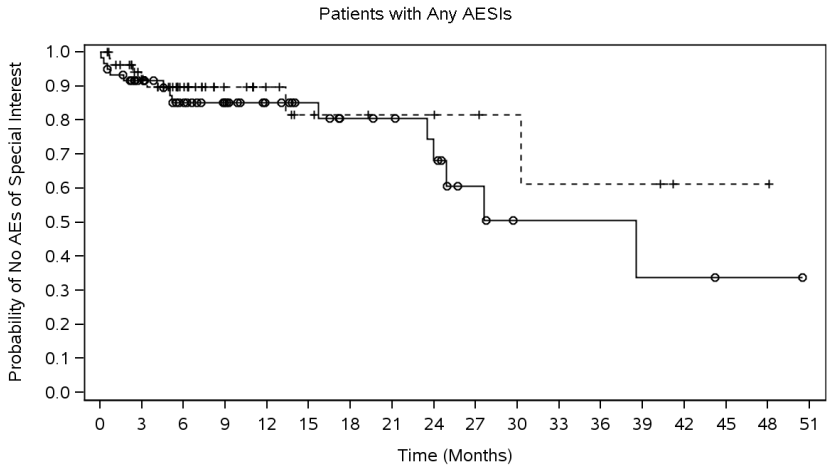
Number of Subjects at Risk

E-Pd	60	51	41	34	26	21	18	17	16	9	6	5	4	2	2	1	1	0
Pd	55	42	28	17	11	7	6	5	5	4	3	3	3	3	1	1	1	0

E-Pd (events: 11/60), median and 95% CI: N.A. (N.A., N.A.)
Pd (events: 12/55), median and 95% CI: N.A. (40.25, N.A.)
Hazard Ratio (E-Pd vs Pd) and 95% CI: 0.660 (0.287, 1.520)

G.6: Darstellung der Kaplan-Meier-Kurven für UE von besonderem Interesse

Kaplan-Meier-Kurve für jegliche UE von besonderem Interesse

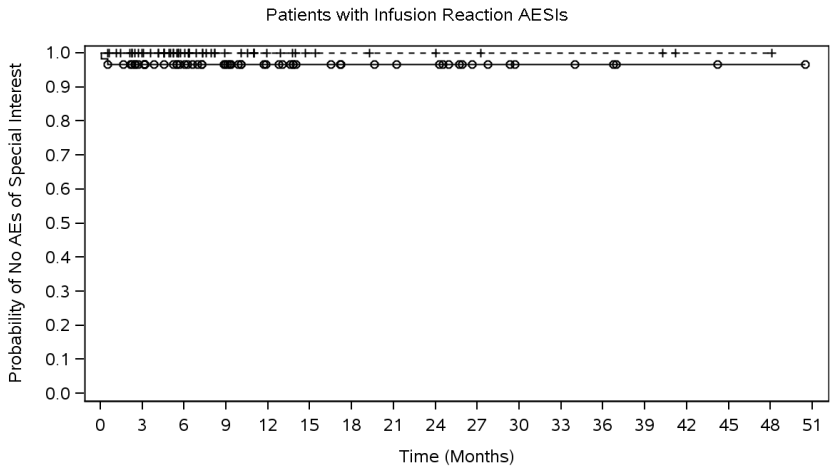


Number of Subjects at Risk

E-Pd	60	48	36	29	23	19	15	14	11	6	3	3	3	2	2	1	1	0
Pd	55	41	28	17	12	8	7	6	6	5	4	3	3	3	1	1	1	0

E-Pd (events: 14/60), median and 95% CI: 38.54 (23.95, N.A.)
Pd (events: 7/55), median and 95% CI: N.A. (30.26, N.A.)
Hazard Ratio (E-Pd vs Pd) and 95% CI: 2.071 (0.737, 5.817)

Kaplan-Meier-Kurve für Infusionsreaktionen

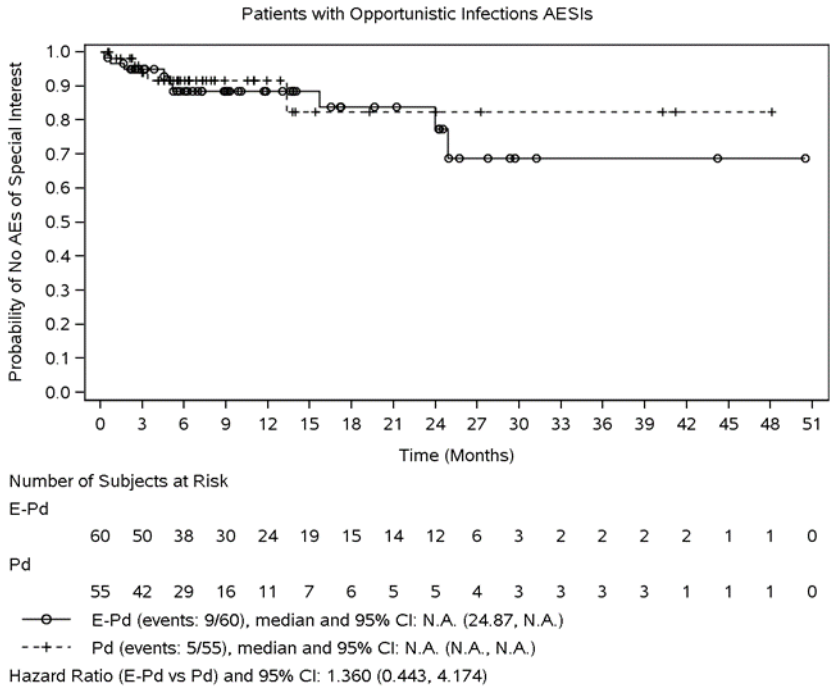


Number of Subjects at Risk

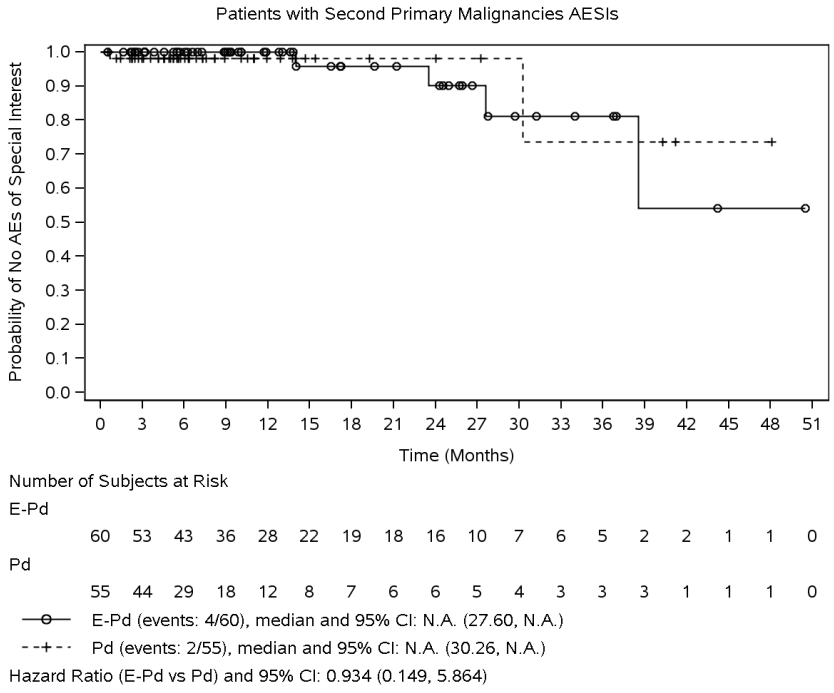
E-Pd	60	51	41	33	25	19	16	15	14	8	5	5	4	2	2	1	1	0
Pd	55	45	30	17	11	7	6	5	5	4	3	3	3	3	1	1	1	0

E-Pd (events: 2/60), median and 95% CI: N.A. (N.A., N.A.)
Pd (events: 0/55), median and 95% CI: N.A. (N.A., N.A.)
Hazard Ratio (E-Pd vs Pd) and 95% CI: N.M.E.

Kaplan-Meier-Kurve für opportunistische Infektionen

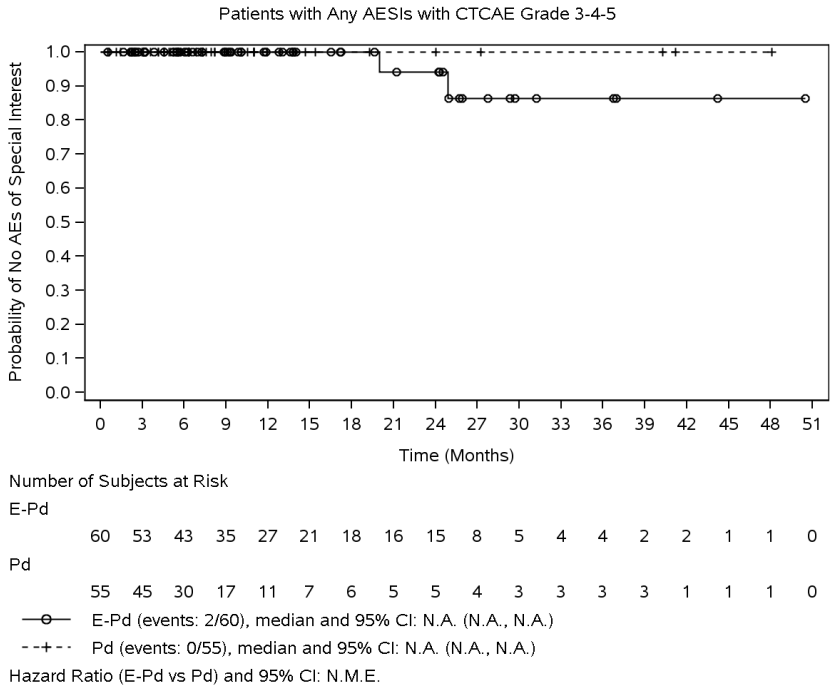


Kaplan-Meier-Kurve für zweite Primärtumore

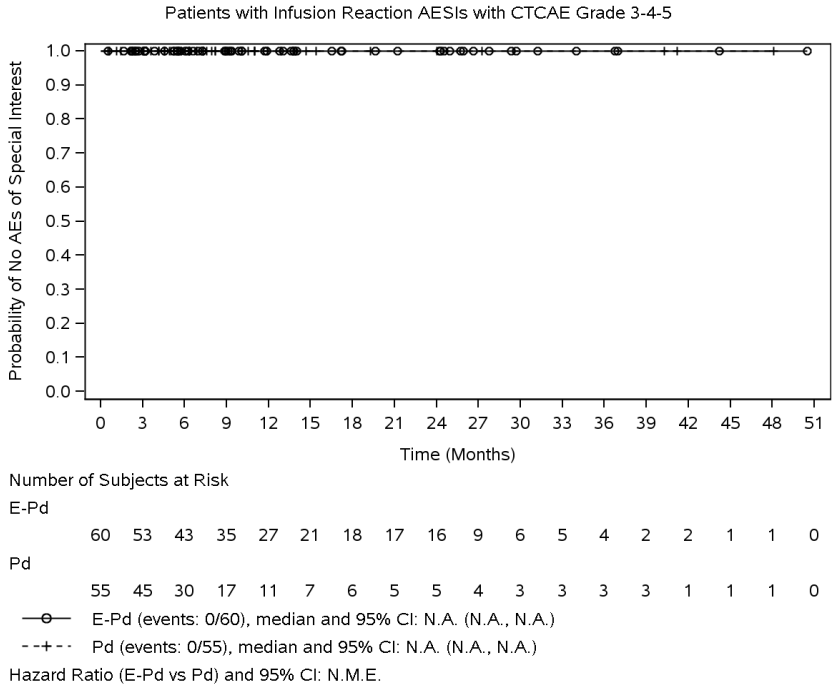


G.7: Darstellung der Kaplan-Meier-Kurven für schwere UE (CTCAE-Grad ≥ 3) von besonderem Interesse

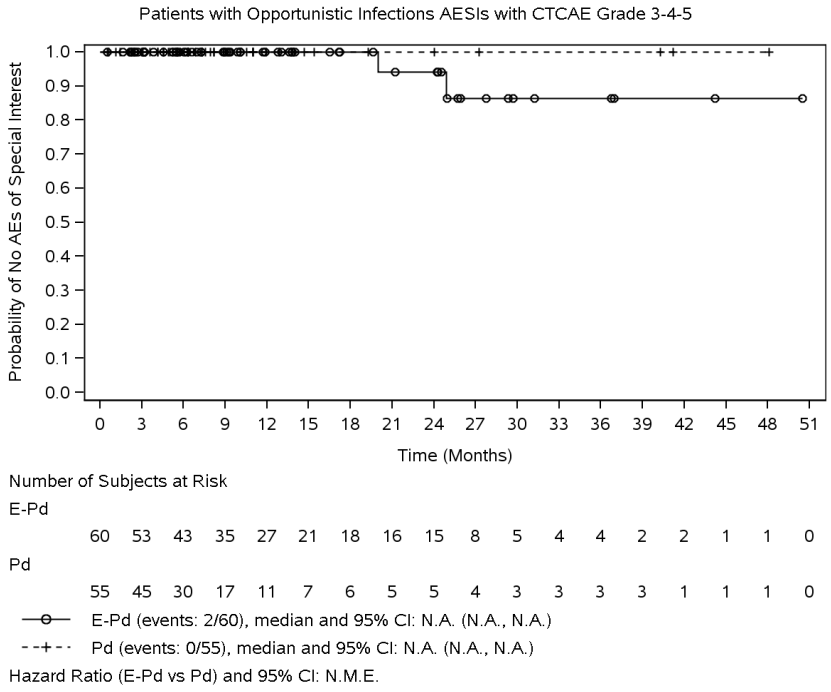
Kaplan-Meier-Kurve für schwere UE (CTCAE-Grad ≥ 3) von besonderem Interesse



Kaplan-Meier-Kurve für Infusionsreaktionen (CTCAE-Grad ≥ 3)

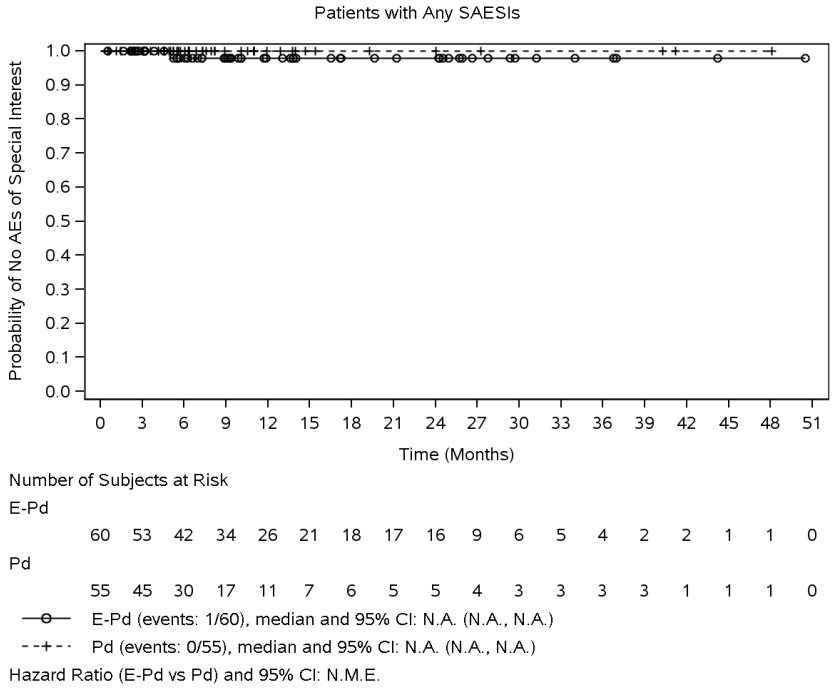


Kaplan-Meier-Kurve für opportunistische Infektionen (CTCAE-Grad ≥ 3)

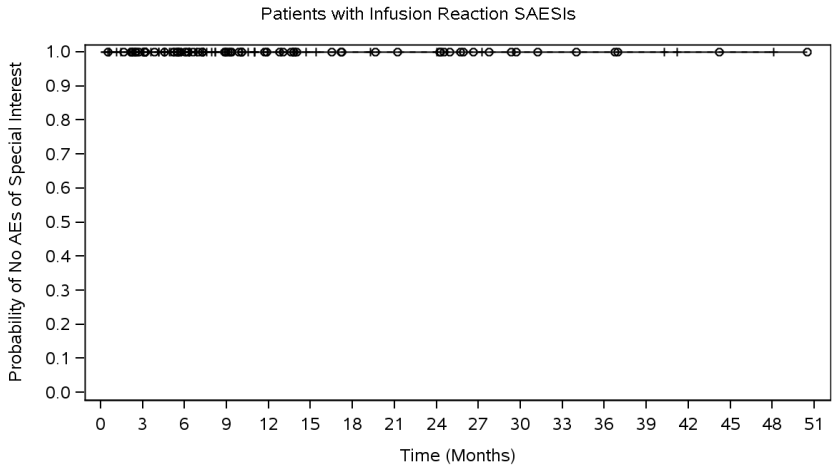


G.8: Darstellung der Kaplan-Meier-Kurven für schwerwiegende UE von besonderem Interesse

Kaplan-Meier-Kurve für schwerwiegende UE von besonderem Interesse



Kaplan-Meier-Kurve für schwerwiegende Infusionsreaktionen

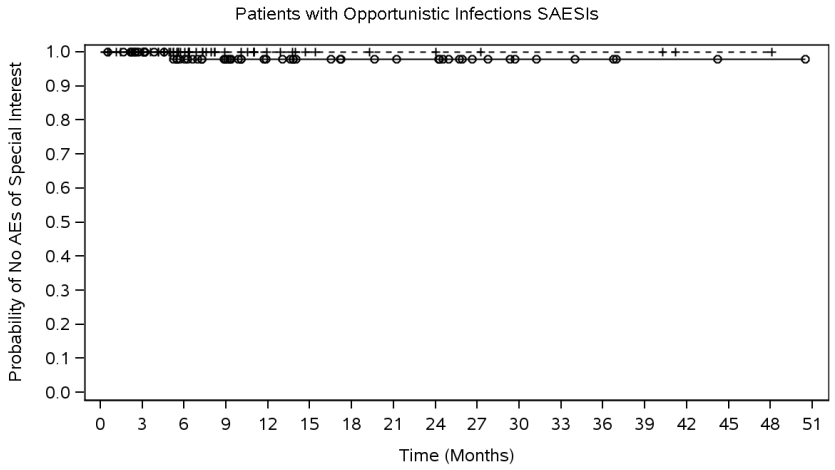


Number of Subjects at Risk

E-Pd	60	53	43	35	27	21	18	17	16	9	6	5	4	2	2	1	1	0
Pd	55	45	30	17	11	7	6	5	5	4	3	3	3	3	1	1	1	0

E-Pd (events: 0/60), median and 95% CI: N.A. (N.A., N.A.)
Pd (events: 0/55), median and 95% CI: N.A. (N.A., N.A.)
Hazard Ratio (E-Pd vs Pd) and 95% CI: N.M.E.

Kaplan-Meier-Kurve für schwerwiegende opportunistische Infektionen



Number of Subjects at Risk

E-Pd	60	53	42	34	26	21	18	17	16	9	6	5	4	2	2	1	1	0
Pd	55	45	30	17	11	7	6	5	5	4	3	3	3	3	1	1	1	0

E-Pd (events: 1/60), median and 95% CI: N.A. (N.A., N.A.)
Pd (events: 0/55), median and 95% CI: N.A. (N.A., N.A.)
Hazard Ratio (E-Pd vs Pd) and 95% CI: N.M.E.

G.9: Darstellung jeglicher UE, schwerer UE (CTCAE-Grad ≥ 3), SUE und zum Therapieabbruch führender UE auf SOC/PT-Ebene

Protocol: CA204125 Page 1 of 6

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

	E-Pd				Pd				E-Pd vs. Pd	
System Organ Class (%) Preferred Term (%)	N	Patients with Event n (%)	Censored Patients n (%)	KME [95%CI] (mon) (1)	N	Patients with Event n (%)	Censored Patients n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	60	58 (96.7)	2 (3.3)	0.23 (0.10, 0.26)	55	53 (96.4)	2 (3.6)	0.10 (0.03, 0.26)	0.838 (0.569, 1.233)	0.4565
INFECTIONS AND INFESTATIONS	60	42 (70.0)	18 (30.0)	5.06 (1.84, 7.29)	55	36 (65.5)	19 (34.5)	3.32 (1.81, 5.45)	0.826 (0.514, 1.325)	0.4270
NASOPHARYNGITIS	60	15 (25.0)	45 (75.0)	N.A. (19.48, N.A.)	55	9 (16.4)	46 (83.6)	14.42 (12.71, N.A.)	0.848 (0.349, 2.061)	0.7166
RESPIRATORY TRACT INFECTION	60	12 (20.0)	48 (80.0)	N.A. (18.43, N.A.)	55	6 (10.9)	49 (89.1)	N.A. (12.19, N.A.)	1.363 (0.502, 3.704)	0.5421
BRONCHITIS	60	10 (16.7)	50 (83.3)	N.A. (20.27, N.A.)	55	6 (10.9)	49 (89.1)	41.95 (N.A., N.A.)	1.089 (0.375, 3.161)	0.8751
UPPER RESPIRATORY TRACT INFECTION	60	8 (13.3)	52 (86.7)	N.A. (N.A., N.A.)	55	9 (16.4)	46 (83.6)	N.A. (18.40, N.A.)	0.574 (0.211, 1.560)	0.2722
PNEUMONIA	60	6 (10.0)	54 (90.0)	N.A. (N.A., N.A.)	55	7 (12.7)	48 (87.3)	N.A. (N.A., N.A.)	0.469 (0.153, 1.436)	0.1758
BLOOD AND LYMPHATIC SYSTEM DISORDERS	60	34 (56.7)	26 (43.3)	5.22 (0.95, 20.44)	55	33 (60.0)	22 (40.0)	2.40 (0.72, 35.91)	0.881 (0.540, 1.438)	0.6412

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:20:54

Protocol: CA204125 Page 2 of 6

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
ANAEMIA	60	17 (28.3)	43 (71.7)	N.A. (N.A., N.A.)	55	21 (38.2)	34 (61.8)	N.A. (3.75, N.A.)	0.609 (0.318, 1.164)	0.1425
NEUTROPENIA	60	16 (26.7)	44 (73.3)	N.A. (20.44, N.A.)	55	17 (30.9)	38 (69.1)	N.A. (8.44, N.A.)	0.808 (0.405, 1.612)	0.5434
THROMBOCYTOPENIA	60	10 (16.7)	50 (83.3)	N.A. (N.A., N.A.)	55	11 (20.0)	44 (80.0)	N.A. (N.A., N.A.)	0.710 (0.293, 1.718)	0.4452
LYMPHOPENIA	60	6 (10.0)	54 (90.0)	N.A. (N.A., N.A.)	55	1 (1.8)	54 (98.2)	N.A. (N.A., N.A.)	5.936 (0.714, 49.326)	0.0615
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	60	33 (55.0)	27 (45.0)	8.77 (2.50, 23.89)	55	28 (50.9)	27 (49.1)	8.38 (1.87, N.A.)	0.919 (0.544, 1.550)	0.7308
PYREXIA	60	12 (20.0)	48 (80.0)	N.A. (23.89, N.A.)	55	15 (27.3)	40 (72.7)	N.A. (8.38, N.A.)	0.671 (0.308, 1.462)	0.3074
FATIGUE	60	11 (18.3)	49 (81.7)	N.A. (23.89, N.A.)	55	9 (16.4)	46 (83.6)	N.A. (N.A., N.A.)	0.762 (0.309, 1.880)	0.5546
OEDEMA PERIPHERAL	60	11 (18.3)	49 (81.7)	N.A. (N.A., N.A.)	55	5 (9.1)	50 (90.9)	N.A. (18.46, N.A.)	1.704 (0.587, 4.945)	0.3213

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:20:54

Protocol: CA204125 Page 3 of 6

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
ASTHENIA	60	8 (13.3)	52 (86.7)	N.A. (N.A., N.A.)	55	5 (9.1)	50 (90.9)	N.A. (N.A., N.A.)	1.427 (0.461, 4.421)	0.5358
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	60	33 (55.0)	27 (45.0)	7.39 (2.96, 28.58)	55	24 (43.6)	31 (56.4)	10.38 (3.52, N.A.)	0.982 (0.564, 1.712)	0.9435
BONE PAIN	60	11 (18.3)	49 (81.7)	N.A. (N.A., N.A.)	55	5 (9.1)	50 (90.9)	N.A. (N.A., N.A.)	1.928 (0.666, 5.577)	0.2162
MUSCLE SPASMS	60	9 (15.0)	51 (85.0)	N.A. (N.A., N.A.)	55	4 (7.3)	51 (92.7)	N.A. (N.A., N.A.)	1.859 (0.562, 6.156)	0.3027
BACK PAIN	60	6 (10.0)	54 (90.0)	N.A. (32.53, N.A.)	55	5 (9.1)	50 (90.9)	N.A. (12.32, N.A.)	0.552 (0.146, 2.083)	0.3741
ARTHRALGIA	60	4 (6.7)	56 (93.3)	N.A. (N.A., N.A.)	55	8 (14.5)	47 (85.5)	N.A. (12.71, N.A.)	0.285 (0.082, 0.991)	0.0371
GASTROINTESTINAL DISORDERS	60	29 (48.3)	31 (51.7)	13.14 (5.55, N.A.)	55	21 (38.2)	34 (61.8)	16.03 (3.29, N.A.)	1.001 (0.564, 1.779)	0.9954
DIARRHOEA	60	15 (25.0)	45 (75.0)	N.A. (14.85, N.A.)	55	7 (12.7)	48 (87.3)	N.A. (16.03, N.A.)	1.321 (0.527, 3.313)	0.5518

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:20:54

Protocol: CA204125 Page 4 of 6

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
CONSTIPATION	60	14 (23.3)	46 (76.7)	N.A. (N.A., N.A.)	55	6 (10.9)	49 (89.1)	N.A. (N.A., N.A.)	1.920 (0.734, 5.022)	0.1755
METABOLISM AND NUTRITION DISORDERS	60	26 (43.3)	34 (56.7)	20.04 (4.63, N.A.)	55	25 (45.5)	30 (54.5)	12.85 (2.79, N.A.)	0.833 (0.476, 1.458)	0.5098
HYPERGLYCAEMIA	60	13 (21.7)	47 (78.3)	N.A. (N.A., N.A.)	55	11 (20.0)	44 (80.0)	N.A. (12.85, N.A.)	0.904 (0.397, 2.058)	0.7970
HYPOKALAEMIA	60	7 (11.7)	53 (88.3)	N.A. (N.A., N.A.)	55	7 (12.7)	48 (87.3)	N.A. (N.A., N.A.)	0.571 (0.187, 1.741)	0.3187
DECREASED APPETITE	60	6 (10.0)	54 (90.0)	N.A. (27.33, N.A.)	55	4 (7.3)	51 (92.7)	N.A. (13.17, N.A.)	1.018 (0.277, 3.746)	0.9782
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	60	19 (31.7)	41 (68.3)	N.A. (12.19, N.A.)	55	15 (27.3)	40 (72.7)	N.A. (N.A., N.A.)	1.082 (0.546, 2.143)	0.8206
DYSPNOEA	60	9 (15.0)	51 (85.0)	N.A. (N.A., N.A.)	55	4 (7.3)	51 (92.7)	N.A. (N.A., N.A.)	2.054 (0.624, 6.762)	0.2268
NERVOUS SYSTEM DISORDERS	60	17 (28.3)	43 (71.7)	N.A. (17.45, N.A.)	55	16 (29.1)	39 (70.9)	N.A. (10.38, N.A.)	0.700 (0.342, 1.431)	0.3251

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:20:54

Protocol: CA204125 Page 5 of 6

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
PSYCHIATRIC DISORDERS	60	16 (26.7)	44 (73.3)	N.A. (16.36, N.A.)	55	12 (21.8)	43 (78.2)	N.A. (9.66, N.A.)	0.916 (0.420, 1.997)	0.8268
INSOMNIA	60	10 (16.7)	50 (83.3)	N.A. (N.A., N.A.)	55	7 (12.7)	48 (87.3)	N.A. (N.A., N.A.)	0.917 (0.338, 2.492)	0.8655
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	60	13 (21.7)	47 (78.3)	N.A. (N.A., N.A.)	55	12 (21.8)	43 (78.2)	N.A. (39.95, N.A.)	0.808 (0.359, 1.819)	0.6018
RASH	60	6 (10.0)	54 (90.0)	N.A. (27.76, N.A.)	55	6 (10.9)	49 (89.1)	N.A. (N.A., N.A.)	0.743 (0.235, 2.344)	0.6107
INVESTIGATIONS	60	9 (15.0)	51 (85.0)	N.A. (N.A., N.A.)	55	18 (32.7)	37 (67.3)	N.A. (7.43, N.A.)	0.468 (0.206, 1.065)	0.0625
BLOOD CREATININE INCREASED	60	4 (6.7)	56 (93.3)	N.A. (N.A., N.A.)	55	6 (10.9)	49 (89.1)	N.A. (N.A., N.A.)	0.564 (0.153, 2.081)	0.3836
VASCULAR DISORDERS	60	9 (15.0)	51 (85.0)	N.A. (N.A., N.A.)	55	5 (9.1)	50 (90.9)	N.A. (N.A., N.A.)	1.305 (0.424, 4.016)	0.6421
CARDIAC DISORDERS	60	7 (11.7)	53 (88.3)	N.A. (N.A., N.A.)	55	7 (12.7)	48 (87.3)	N.A. (18.43, N.A.)	0.772 (0.268, 2.227)	0.6315

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:20:54

Protocol: CA204125 Page 6 of 6

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
EYE DISORDERS	60	7 (11.7)	53 (88.3)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	1.608 (0.412, 6.266)	0.4900
CATARACT	60	6 (10.0)	54 (90.0)	N.A. (N.A., N.A.)	55	0	55 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0506
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	60	7 (11.7)	53 (88.3)	N.A. (25.23, N.A.)	55	10 (18.2)	45 (81.8)	N.A. (11.63, N.A.)	0.535 (0.193, 1.487)	0.2240
RENAL AND URINARY DISORDERS	60	6 (10.0)	54 (90.0)	N.A. (N.A., N.A.)	55	11 (20.0)	44 (80.0)	N.A. (24.08, N.A.)	0.381 (0.137, 1.058)	0.0556
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	60	3 (5.0)	57 (95.0)	N.A. (N.A., N.A.)	55	13 (23.6)	42 (76.4)	40.25 (40.25, N.A.)	0.109 (0.024, 0.491)	0.0006
MALIGNANT NEOPLASM PROGRESSION	60	1 (1.7)	59 (98.3)	N.A. (N.A., N.A.)	55	7 (12.7)	48 (87.3)	N.A. (N.A., N.A.)	0.109 (0.013, 0.900)	0.0133
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	60	3 (5.0)	57 (95.0)	N.A. (26.25, N.A.)	55	6 (10.9)	49 (89.1)	N.A. (34.07, N.A.)	0.209 (0.042, 1.054)	0.0374

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:20:54

Protocol: CA204125 Page 1 of 4

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events with CTCAE Grade 3-4-5
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
TOTAL SUBJECTS WITH AN EVENT	60	44 (73.3)	16 (26.7)	2.86 (0.72, 9.20)	55	45 (81.8)	10 (18.2)	0.72 (0.69, 1.87)	0.618 (0.399, 0.958)	0.0315
BLOOD AND LYMPHATIC SYSTEM DISORDERS	60	25 (41.7)	35 (58.3)	18.89 (9.20, N.A.)	55	24 (43.6)	31 (56.4)	N.A. (2.00, N.A.)	0.869 (0.492, 1.537)	0.6349
NEUTROPENIA	60	9 (15.0)	51 (85.0)	N.A. (N.A., N.A.)	55	15 (27.3)	40 (72.7)	N.A. (N.A., N.A.)	0.498 (0.217, 1.146)	0.0917
ANAEMIA	60	7 (11.7)	53 (88.3)	N.A. (N.A., N.A.)	55	12 (21.8)	43 (78.2)	N.A. (13.34, N.A.)	0.423 (0.165, 1.089)	0.0665
THROMBOCYTOPENIA	60	6 (10.0)	54 (90.0)	N.A. (N.A., N.A.)	55	4 (7.3)	51 (92.7)	N.A. (N.A., N.A.)	1.104 (0.296, 4.121)	0.8826
LEUKOPENIA	60	5 (8.3)	55 (91.7)	N.A. (N.A., N.A.)	55	2 (3.6)	53 (96.4)	N.A. (N.A., N.A.)	2.346 (0.455, 12.095)	0.2955
LYMPHOPENIA	60	5 (8.3)	55 (91.7)	N.A. (N.A., N.A.)	55	1 (1.8)	54 (98.2)	N.A. (N.A., N.A.)	4.468 (0.520, 38.362)	0.1351
FEBRILE NEUTROPENIA	60	3 (5.0)	57 (95.0)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	0.638 (0.127, 3.209)	0.5829

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:21:09

Protocol: CA204125 Page 2 of 4

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events with CTCAE Grade 3-4-5
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
INFECTIONS AND INFESTATIONS	60	19 (31.7)	41 (68.3)	24.87 (17.31, N.A.)	55	15 (27.3)	40 (72.7)	N.A. (12.19, N.A.)	0.734 (0.364, 1.478)	0.3865
PNEUMONIA	60	4 (6.7)	56 (93.3)	N.A. (N.A., N.A.)	55	6 (10.9)	49 (89.1)	N.A. (N.A., N.A.)	0.413 (0.113, 1.506)	0.1680
LOWER RESPIRATORY TRACT INFECTION	60	3 (5.0)	57 (95.0)	N.A. (28.58, N.A.)	55	0	55 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.2436
SEPTIC SHOCK	60	2 (3.3)	58 (96.7)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	0.443 (0.072, 2.724)	0.3679
METABOLISM AND NUTRITION DISORDERS	60	10 (16.7)	50 (83.3)	N.A. (28.58, N.A.)	55	13 (23.6)	42 (76.4)	N.A. (12.85, N.A.)	0.598 (0.260, 1.376)	0.2223
HYPERGLYCAEMIA	60	5 (8.3)	55 (91.7)	N.A. (N.A., N.A.)	55	6 (10.9)	49 (89.1)	N.A. (N.A., N.A.)	0.660 (0.200, 2.177)	0.4947
HYPOKALAEMIA	60	2 (3.3)	58 (96.7)	N.A. (28.58, N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	0.456 (0.074, 2.833)	0.3890
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	60	8 (13.3)	52 (86.7)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	2.095 (0.550, 7.978)	0.2677

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:21:09

Protocol: CA204125 Page 3 of 4

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events with CTCAE Grade 3-4-5
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
EYE DISORDERS	60	6 (10.0)	54 (90.0)	N.A. (26.35, N.A.)	55	0	55 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0740
CATARACT	60	5 (8.3)	55 (91.7)	N.A. (28.45, N.A.)	55	0	55 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.1120
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	60	6 (10.0)	54 (90.0)	N.A. (24.94, N.A.)	55	7 (12.7)	48 (87.3)	N.A. (18.46, N.A.)	0.389 (0.119, 1.270)	0.1065
CARDIAC DISORDERS	60	5 (8.3)	55 (91.7)	N.A. (N.A., N.A.)	55	4 (7.3)	51 (92.7)	N.A. (18.60, N.A.)	0.887 (0.234, 3.364)	0.8594
INVESTIGATIONS	60	4 (6.7)	56 (93.3)	N.A. (N.A., N.A.)	55	8 (14.5)	47 (85.5)	N.A. (N.A., N.A.)	0.424 (0.125, 1.437)	0.1567
NEUTROPHIL COUNT DECREASED	60	3 (5.0)	57 (95.0)	N.A. (N.A., N.A.)	55	5 (9.1)	50 (90.9)	N.A. (N.A., N.A.)	0.548 (0.131, 2.294)	0.4039
PLATELET COUNT DECREASED	60	3 (5.0)	57 (95.0)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (13.34, N.A.)	0.701 (0.136, 3.600)	0.6686
PSYCHIATRIC DISORDERS	60	4 (6.7)	56 (93.3)	N.A. (N.A., N.A.)	55	1 (1.8)	54 (98.2)	N.A. (N.A., N.A.)	2.515 (0.276, 22.913)	0.3975

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:21:09

Protocol: CA204125 Page 4 of 4

Time-Adjusted Analyses of Adverse Events for
On-Study Adverse Events with CTCAE Grade 3-4-5
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
GASTROINTESTINAL DISORDERS	60	3 (5.0)	57 (95.0)	N.A. (N.A., N.A.)	55	1 (1.8)	54 (98.2)	N.A. (N.A., N.A.)	1.432 (0.126, 16.263)	0.7711
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	60	3 (5.0)	57 (95.0)	N.A. (N.A., N.A.)	55	1 (1.8)	54 (98.2)	N.A. (N.A., N.A.)	2.098 (0.214, 20.585)	0.5158
NERVOUS SYSTEM DISORDERS	60	3 (5.0)	57 (95.0)	40.05 (40.05, N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	0.931 (0.185, 4.675)	0.9307
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	60	2 (3.3)	58 (96.7)	N.A. (N.A., N.A.)	55	11 (20.0)	44 (80.0)	N.A. (40.25, N.A.)	0.067 (0.008, 0.527)	0.0008
MALIGNANT NEOPLASM PROGRESSION	60	1 (1.7)	59 (98.3)	N.A. (N.A., N.A.)	55	7 (12.7)	48 (87.3)	N.A. (N.A., N.A.)	0.109 (0.013, 0.900)	0.0133
RENAL AND URINARY DISORDERS	60	1 (1.7)	59 (98.3)	N.A. (N.A., N.A.)	55	4 (7.3)	51 (92.7)	N.A. (24.08, N.A.)	0.180 (0.020, 1.627)	0.0867

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:21:09

Protocol: CA204125 Page 1 of 3

Time-Adjusted Analyses of Adverse Events for
On-study Serious Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
TOTAL SUBJECTS WITH AN EVENT	60	42 (70.0)	18 (30.0)	9.20 (3.12, 15.21)	55	33 (60.0)	22 (40.0)	5.09 (2.43, 18.60)	0.865 (0.531, 1.411)	0.5624
INFECTIONS AND INFESTATIONS	60	25 (41.7)	35 (58.3)	19.94 (12.45, N.A.)	55	15 (27.3)	40 (72.7)	N.A. (8.77, N.A.)	1.060 (0.545, 2.060)	0.8595
RESPIRATORY TRACT INFECTION	60	5 (8.3)	55 (91.7)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	1.012 (0.229, 4.473)	0.9870
PNEUMONIA	60	4 (6.7)	56 (93.3)	N.A. (N.A., N.A.)	55	5 (9.1)	50 (90.9)	N.A. (N.A., N.A.)	0.488 (0.128, 1.868)	0.2860
LOWER RESPIRATORY TRACT INFECTION	60	3 (5.0)	57 (95.0)	N.A. (28.58, N.A.)	55	1 (1.8)	54 (98.2)	N.A. (22.08, N.A.)	0.885 (0.070, 11.195)	0.9251
SEPTIC SHOCK	60	2 (3.3)	58 (96.7)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	0.443 (0.072, 2.724)	0.3679
BLOOD AND LYMPHATIC SYSTEM DISORDERS	60	6 (10.0)	54 (90.0)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	1.555 (0.385, 6.282)	0.5326
FEBRILE NEUTROPENIA	60	3 (5.0)	57 (95.0)	N.A. (N.A., N.A.)	55	2 (3.6)	53 (96.4)	N.A. (N.A., N.A.)	0.987 (0.162, 6.005)	0.9884

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:21:16

Protocol: CA204125 Page 2 of 3

Time-Adjusted Analyses of Adverse Events for
On-study Serious Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
CARDIAC DISORDERS	60	4 (6.7)	56 (93.3)	N.A. (N.A., N.A.)	55	4 (7.3)	51 (92.7)	N.A. (18.60, N.A.)	0.722 (0.178, 2.928)	0.6469
EYE DISORDERS	60	4 (6.7)	56 (93.3)	N.A. (26.35, N.A.)	55	0	55 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.1916
CATARACT	60	3 (5.0)	57 (95.0)	N.A. (28.45, N.A.)	55	0	55 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3074
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	60	4 (6.7)	56 (93.3)	N.A. (N.A., N.A.)	55	1 (1.8)	54 (98.2)	N.A. (N.A., N.A.)	2.532 (0.277, 23.171)	0.3949
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	60	3 (5.0)	57 (95.0)	N.A. (N.A., N.A.)	55	6 (10.9)	49 (89.1)	N.A. (N.A., N.A.)	0.382 (0.094, 1.549)	0.1625
PYREXIA	60	1 (1.7)	59 (98.3)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	0.279 (0.029, 2.707)	0.2401
METABOLISM AND NUTRITION DISORDERS	60	3 (5.0)	57 (95.0)	N.A. (N.A., N.A.)	55	0	55 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0920

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:21:16

Protocol: CA204125 Page 3 of 3

Time-Adjusted Analyses of Adverse Events for
On-study Serious Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N	E-Pd Patients with Event n (%)	E-Pd Censored Patients n (%)	E-Pd KME [95%CI] (mon) (1)	Pd N	Pd Patients with Event n (%)	Pd Censored Patients n (%)	Pd KME [95%CI] (mon) (1)	E-Pd vs. Pd HR [95%CI] (2)	E-Pd vs. Pd P-value (3)
NERVOUS SYSTEM DISORDERS	60	3 (5.0)	57 (95.0)	40.05 (40.05, N.A.)	55	2 (3.6)	53 (96.4)	N.A. (N.A., N.A.)	1.218 (0.194, 7.654)	0.8331
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	60	2 (3.3)	58 (96.7)	N.A. (N.A., N.A.)	55	12 (21.8)	43 (78.2)	40.25 (40.25, N.A.)	0.061 (0.008, 0.479)	0.0004
MALIGNANT NEOPLASM PROGRESSION	60	1 (1.7)	59 (98.3)	N.A. (N.A., N.A.)	55	7 (12.7)	48 (87.3)	N.A. (N.A., N.A.)	0.109 (0.013, 0.900)	0.0133
RENAL AND URINARY DISORDERS	60	2 (3.3)	58 (96.7)	N.A. (N.A., N.A.)	55	6 (10.9)	49 (89.1)	N.A. (24.08, N.A.)	0.241 (0.048, 1.226)	0.0647
ACUTE KIDNEY INJURY	60	2 (3.3)	58 (96.7)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	0.492 (0.079, 3.056)	0.4379
RENAL FAILURE	60	0	60 (100.0)	N.A. (N.A., N.A.)	55	3 (5.5)	52 (94.5)	N.A. (N.A., N.A.)	N.M.E.	0.0724

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no subjects with events in E-Pd or Pd, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is E-Pd over Pd.
(3) Log-rank Test stratified by stage of disease at study entry (International Staging System I-II vs III) and number of prior lines of therapy (2-3 vs >=4) at randomization as entered into the IVRS.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taegr-ebr2453.sas 30MAR2021:10:21:16

Protocol: CA204125 Page 1 of 2

On-study Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) Preferred Term (%)	E-Pd N = 60			Pd N = 55		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	11 (18.3)	7 (11.7)	3 (5.0)	13 (23.6)	6 (10.9)	4 (7.3)
Infections and infestations	5 (8.3)	4 (6.7)	1 (1.7)	1 (1.8)	0	1 (1.8)
Lower respiratory tract infection	1 (1.7)	1 (1.7)	0	0	0	0
Pneumococcal sepsis	1 (1.7)	0	1 (1.7)	0	0	0
Pneumonia	1 (1.7)	1 (1.7)	0	0	0	0
Progressive multifocal leukoencephalopathy	1 (1.7)	1 (1.7)	0	0	0	0
Respiratory syncytial virus infection	1 (1.7)	1 (1.7)	0	0	0	0
Septic shock	0	0	0	1 (1.8)	0	1 (1.8)
Cardiac disorders	1 (1.7)	0	1 (1.7)	1 (1.8)	0	1 (1.8)
Cardiac failure	1 (1.7)	0	1 (1.7)	0	0	0
Myocardial infarction	0	0	0	1 (1.8)	0	1 (1.8)
Ear and labyrinth disorders	1 (1.7)	0	0	0	0	0
Deafness	1 (1.7)	0	0	0	0	0
Eye disorders	1 (1.7)	1 (1.7)	0	0	0	0
Cataract	1 (1.7)	1 (1.7)	0	0	0	0
General disorders and administration site conditions	1 (1.7)	0	1 (1.7)	2 (3.6)	1 (1.8)	0
General physical health deterioration	1 (1.7)	0	1 (1.7)	0	0	0
Disease progression	0	0	0	1 (1.8)	1 (1.8)	0
Pyrexia	0	0	0	1 (1.8)	0	0
Immune system disorders	1 (1.7)	1 (1.7)	0	0	0	0
Amyloidosis	1 (1.7)	1 (1.7)	0	0	0	0

DBL - 22FEB2021. MedDRA Version: 23.0 CTC Version 4.0
Includes events reported between first dose and 60 days after last dose of study therapy.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltd-ebr2453.sas 30MAR2021:10:23:29

Protocol: CA204125

On-study Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) / Preferred Term (%)	E-Pd N = 60			Pd N = 55		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Nervous system disorders	1 (1.7)	0	0	1 (1.8)	1 (1.8)	0
Amnesia	1 (1.7)	0	0	0	0	0
Tremor	1 (1.7)	0	0	0	0	0
Cerebrovascular accident	0	0	0	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders	1 (1.7)	0	0	0	0	0
Pleural effusion	1 (1.7)	0	0	0	0	0
Vascular disorders	1 (1.7)	1 (1.7)	0	0	0	0
Peripheral ischaemia	1 (1.7)	1 (1.7)	0	0	0	0
Blood and lymphatic system disorders	0	0	0	1 (1.8)	1 (1.8)	0
Febrile neutropenia	0	0	0	1 (1.8)	1 (1.8)	0
Investigations	0	0	0	1 (1.8)	1 (1.8)	0
Neutrophil count decreased	0	0	0	1 (1.8)	1 (1.8)	0
Metabolism and nutrition disorders	0	0	0	2 (3.6)	0	0
Hypercalcaemia	0	0	0	2 (3.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	3 (5.5)	1 (1.8)	2 (3.6)
Invasive breast carcinoma	0	0	0	1 (1.8)	0	1 (1.8)
Lung neoplasm malignant	0	0	0	1 (1.8)	0	1 (1.8)
Plasma cell leukaemia	0	0	0	1 (1.8)	1 (1.8)	0
Renal and urinary disorders	0	0	0	2 (3.6)	1 (1.8)	0
Acute kidney injury	0	0	0	1 (1.8)	1 (1.8)	0
Renal failure	0	0	0	1 (1.8)	0	0

DBL - 22FEB2021. MedDRA Version: 23.0 CTC Version 4.0
Includes events reported between first dose and 60 days after last dose of study therapy.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltd-ebr2453.sas 30MAR2021:10:23:29

G.10: Darstellung aller Subgruppenanalysen

Subgruppenergebnisse für den Endpunkt Gesamtüberleben

Protocol: CA204125 Page 1 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
OVERALL	60	37 (61.7)	29.80 (22.87, 45.67)	57	41 (71.9)	17.41 (13.83, 27.70)	0.638 (0.408, 0.997) 0.0468	
AGE I								0.2419
< 75	47	30 (63.8)	28.29 (18.04, 45.67)	45	31 (68.9)	20.83 (12.88, 32.53)	0.725 (0.439, 1.198) 0.2075	
>= 75	13	7 (53.8)	34.43 (3.52, N.A.)	12	10 (83.3)	14.72 (1.45, 25.46)	0.358 (0.127, 1.012) 0.0444	
AGE II								0.6678
< 65	22	12 (54.5)	45.67 (16.66, N.A.)	22	14 (63.6)	19.29 (13.83, 35.06)	0.569 (0.261, 1.240) 0.1506	
>= 65	38	25 (65.8)	26.64 (17.71, 34.43)	35	27 (77.1)	16.76 (8.31, 32.53)	0.700 (0.405, 1.208) 0.1973	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Protocol: CA204125 Page 2 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
AGE III								0.2909
< 65	22	12 (54.5)	45.67 (16.66, N.A.)	22	14 (63.6)	19.29 (13.83, 35.06)	0.569 (0.261, 1.240) 0.1506	
>= 65 AND < 75	25	18 (72.0)	24.94 (13.96, 32.03)	23	17 (73.9)	24.02 (6.80, 40.94)	0.936 (0.481, 1.824) 0.8467	
>= 75	13	7 (53.8)	34.43 (3.52, N.A.)	12	10 (83.3)	14.72 (1.45, 25.46)	0.358 (0.127, 1.012) 0.0444	
RACE								0.4677
WHITE	45	32 (71.1)	24.97 (15.90, 34.14)	45	34 (75.6)	16.89 (8.97, 26.48)	0.747 (0.461, 1.212) 0.2362	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	1	0	N.M.E.	N.M.E.	
ASIAN	15	5 (33.3)	48.59 (31.70, N.A.)	9	5 (55.6)	30.11 (5.75, N.A.)	0.416 (0.119, 1.453) 0.1564	
OTHER	0	0	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Protocol: CA204125 Page 3 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	E-Pd vs. Pd Test for interaction p-value (4)(5)
SEX								0.9705
MALE	32	19 (59.4)	28.29 (15.90, N.A.)	35	25 (71.4)	18.37 (14.52, 27.70)	0.652 (0.359, 1.187) 0.1589	
FEMALE	28	18 (64.3)	31.70 (17.71, 48.92)	22	16 (72.7)	16.43 (5.75, 35.06)	0.637 (0.324, 1.253) 0.1878	
BASELINE B2 MICROGLOBULIN (MG/L)								0.9334
< 3.5	35	17 (48.6)	48.59 (26.64, N.A.)	32	21 (65.6)	27.70 (14.72, 43.04)	0.593 (0.312, 1.125) 0.1058	
>= 3.5	24	19 (79.2)	15.90 (6.60, 28.29)	25	20 (80.0)	14.52 (7.62, 16.89)	0.591 (0.308, 1.135) 0.1106	
NOT REPORTED	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Protocol: CA204125 Page 4 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
ISS STAGE AT STUDY ENTRY (CRF)								0.5282
I-II	53	31 (58.5)	33.58 (25.03, 48.59)	50	35 (70.0)	20.83 (14.72, 32.53)	0.627 (0.386, 1.019) 0.0572	
III	7	6 (85.7)	11.24 (0.53, 15.90)	7	6 (85.7)	8.31 (0.62, 13.83)	0.467 (0.127, 1.717) 0.2421	
BASELINE LDH								0.7145
< 300	43	25 (58.1)	33.58 (24.94, 48.59)	41	28 (68.3)	24.02 (15.97, 36.21)	0.683 (0.398, 1.172) 0.1639	
>= 300	14	10 (71.4)	16.66 (3.35, 31.70)	15	13 (86.7)	12.88 (6.80, 14.72)	0.615 (0.265, 1.427) 0.2539	
NOT REPORTED	3	2 (66.7)	N.M.E.	1	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Protocol: CA204125 Page 5 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
BASELINE CREATININE CLEARANCE (ML/MIN)								0.2117
< 60	14	8 (57.1)	34.43 (3.52, N.A.)	16	13 (81.3)	9.30 (4.21, 25.46)	0.460 (0.184, 1.145) 0.0884	
>= 60	45	29 (64.4)	28.29 (18.04, 45.67)	40	28 (70.0)	24.02 (14.62, 36.21)	0.763 (0.453, 1.283) 0.3058	
NOT REPORTED	1	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NUMBER OF LINES OF PRIOR THERAPY (CRF)								0.2222
2-3	35	22 (62.9)	31.70 (15.90, 45.67)	36	25 (69.4)	19.29 (14.52, 37.13)	0.787 (0.444, 1.397) 0.4123	
>= 4	25	15 (60.0)	29.80 (22.87, 48.92)	21	16 (76.2)	15.97 (7.16, 27.70)	0.423 (0.201, 0.891) 0.0200	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Protocol: CA204125 Page 6 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	E-Pd vs. Pd Test for interaction p-value (4)(5)
REGION								0.0679
NORTH AMERICA	3	2 (66.7)	15.90 (3.52, 15.90)	7	3 (42.9)	41.26 (14.62, N.A.)	7.027 (0.614, 80.430) 0.0717	
EUROPE	44	31 (70.5)	25.03 (16.66, 34.43)	43	34 (79.1)	15.97 (8.31, 26.48)	0.656 (0.402, 1.070) 0.0889	
JAPAN	13	4 (30.8)	48.59 (29.80, N.A.)	7	4 (57.1)	30.11 (5.75, N.A.)	0.335 (0.082, 1.371) 0.1115	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS I								0.5396
0-1	56	34 (60.7)	31.70 (22.87, 48.59)	49	34 (69.4)	20.83 (14.72, 35.06)	0.690 (0.428, 1.111) 0.1246	
2	4	3 (75.0)	17.71 (3.52, 35.09)	8	7 (87.5)	8.31 (0.62, 13.83)	0.378 (0.076, 1.885) 0.2195	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Protocol: CA204125 Page 7 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	E-Pd vs. Pd Test for interaction p-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS II								0.7612
0	28	15 (53.6)	45.67 (21.26, N.A.)	23	15 (65.2)	21.65 (7.59, N.A.)	0.606 (0.296, 1.241) 0.1662	
>= 1	32	22 (68.8)	26.51 (13.96, 34.43)	34	26 (76.5)	16.89 (12.88, 26.48)	0.692 (0.388, 1.234) 0.2093	
PRIOR STEM CELL TRANSPLANT								0.0079**
YES	31	23 (74.2)	26.64 (18.04, 34.14)	33	21 (63.6)	27.70 (13.83, 37.13)	1.053 (0.582, 1.903) 0.8646	
NO	29	14 (48.3)	48.59 (15.70, N.A.)	24	20 (83.3)	14.62 (6.80, 16.89)	0.328 (0.161, 0.670) 0.0014	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Protocol: CA204125 Page 8 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
MYELOMA RISK CATEGORY								0.5926
HIGH RISK	6	6 (100.0)	8.77 (4.96, 48.59)	10	8 (80.0)	8.31 (1.45, 18.37)	0.902 (0.292, 2.784) 0.8574	
LOW RISK	2	2 (100.0)	N.M.E.	1	1 (100.0)	N.M.E.	N.M.E.	
STANDARD RISK	46	24 (52.2)	33.58 (25.03, N.A.)	41	27 (65.9)	25.46 (15.97, 35.06)	0.654 (0.377, 1.134) 0.1275	
NOT EVALUABLE	6	5 (83.3)	30.01 (13.96, N.A.)	5	5 (100.0)	6.80 (0.62, 41.26)	N.M.E.	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 9 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	E-Pd vs. Pd Test for interaction p-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	3 (100.0)	N.M.E.	6	5 (83.3)	N.M.E.	N.M.E.	
NO	47	26 (55.3)	N.M.E.	41	28 (68.3)	N.M.E.	N.M.E.	
NOT REPORTED	10	8 (80.0)	N.M.E.	10	8 (80.0)	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	6 (85.7)	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	
NO	44	24 (54.5)	N.M.E.	44	31 (70.5)	N.M.E.	N.M.E.	
NOT REPORTED	9	7 (77.8)	N.M.E.	11	8 (72.7)	N.M.E.	N.M.E.	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Protocol: CA204125 Page 10 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	E-Pd vs. Pd Test for interaction p-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								0.9710
YES	7	5 (71.4)	21.26 (10.94, 48.59)	10	6 (60.0)	8.31 (1.45, N.A.)	0.459 (0.126, 1.665) 0.2257	
NO	43	24 (55.8)	31.70 (17.71, N.A.)	36	27 (75.0)	20.83 (14.62, 32.53)	0.611 (0.352, 1.062) 0.0778	
NOT REPORTED	10	8 (80.0)	33.08 (12.71, 45.67)	11	8 (72.7)	17.41 (4.01, N.A.)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (1Q21)								0.2295
YES	28	19 (67.9)	21.26 (10.94, 34.43)	30	20 (66.7)	16.76 (7.89, 36.21)	0.858 (0.457, 1.610) 0.6337	
NO	22	10 (45.5)	35.09 (25.03, N.A.)	14	11 (78.6)	20.83 (12.88, 35.06)	0.405 (0.171, 0.962) 0.0346	
NOT REPORTED	10	8 (80.0)	33.08 (12.71, 48.92)	13	10 (76.9)	17.41 (4.21, 41.26)	N.M.E.	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Protocol: CA204125 Page 11 of 11

Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall Survival Subgroup	E-Pd N	E-Pd Patients with event n (%)	E-Pd KME [95% CI](mon) (1)	Pd N	Pd Patients with event n (%)	Pd KME [95% CI](mon) (1)	E-Pd vs. Pd HR [95% CI] p-value (2)(3)	E-Pd vs. Pd Test for interaction p-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	2 (100.0)	N.M.E.	1	1 (100.0)	N.M.E.	N.M.E.	
NO	47	26 (55.3)	N.M.E.	43	30 (69.8)	N.M.E.	N.M.E.	
NOT REPORTED	11	9 (81.8)	N.M.E.	13	10 (76.9)	N.M.E.	N.M.E.	

DBL - 22FEB2021, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
If less than 2 subgroups which individually have 10 or more events, display corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd to Pd. (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub05-ebr2453.sas 31MAR2021:07:54:56

Subgruppenergebnisse für den Endpunkt Gesundheitszustand gemessen anhand des EQ-5D VAS

Table 5.2.2: Subgroup MMRM for EQ-5D: VAS [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
EQ-5D: VAS									
All Patients	52	65.8 (18.9)	3.0 (2.7)	48	69.0 (21.0)	-1.4 (2.9)	4.4 (-1.2, 10.1) 0.1201	0.31 (-0.09, 0.70)	
Age Category I:									0.5659
<75 years	41	67.0 (19.6)	1.6 (2.1)	37	71.0 (20.3)	-3.8 (2.4)	5.4 (-0.9, 11.8) 0.0924	0.38 (-0.07, 0.83)	
>=75 years	11	61.7 (16.1)	-0.9 (4.1)	11	62.3 (23.0)	-2.5 (4.4)	1.6 (-10.4, 13.5) 0.7966	0.10 (-0.73, 0.94)	
Age Category II:									0.3529
<65 years	20	67.9 (20.4)	6.0 (2.9)	18	66.5 (21.8)	-1.7 (3.2)	7.7 (-0.9, 16.4) 0.0793	0.56 (-0.09, 1.21)	
>=65 years	32	64.6 (18.2)	-2.1 (2.4)	30	70.5 (20.8)	-4.7 (2.6)	2.6 (-4.5, 9.6) 0.4715	0.18 (-0.32, 0.68)	
Age Category III:									0.6311
<65 years	20	67.9 (20.4)	6.2 (2.9)	18	66.5 (21.8)	-1.7 (3.3)	7.9 (-0.8, 16.6) 0.0757	0.56 (-0.09, 1.21)	
>=65 - <75 years	21	66.1 (19.4)	-3.1 (2.9)	19	75.2 (18.4)	-5.9 (3.3)	2.8 (-5.9, 11.5) 0.5201	0.20 (-0.42, 0.82)	
>=75 years	11	61.7 (16.1)	-0.6 (4.1)	11	62.3 (23.0)	-2.6 (4.4)	2.0 (-9.8, 13.8) 0.7380	0.14 (-0.70, 0.97)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The EQ-5D VAS score ranges from 0-100 with higher scores associated with better health states.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.2.2 (cont.): Subgroup MMRM for EQ-5D: VAS [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Race :									0.0175
White	37	67.8 (18.5)	-0.6 (2.2)	38	70.2 (19.7)	-1.3 (2.4)	0.7 (-5.9, 7.2) 0.8426	0.04 (-0.41, 0.50)	
Black or African American	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Asian	15	61.1 (19.6)	4.6 (3.3)	8	67.3 (22.7)	-11.5 (4.6)	16.1 (4.8, 27.4) 0.0059	1.18 (0.25, 2.10)	
Other	0	N.M.E.	N.M.E.	2	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Gender:									0.0824
Male	26	67.0 (20.8)	4.4 (2.6)	28	69.6 (15.3)	-4.7 (2.7)	9.1 (1.6, 16.6) 0.0184	0.64 (0.09, 1.18)	
Female	26	64.7 (17.1)	-2.3 (2.7)	20	68.2 (27.5)	-1.8 (3.3)	-0.4 (-8.8, 7.9) 0.9155	-0.03 (-0.61, 0.55)	
Baseline B2 Microglobulin (mg/L):									0.3946
<3.5	32	63.1 (19.7)	0.8 (2.3)	28	73.8 (17.8)	-2.2 (2.6)	3.0 (-4.0, 10.0) 0.3985	0.21 (-0.29, 0.72)	
>=3.5	19	70.8 (17.4)	2.2 (3.1)	20	62.2 (23.7)	-5.8 (3.4)	8.0 (-1.2, 17.1) 0.0886	0.53 (-0.11, 1.17)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The EQ-5D VAS score ranges from 0-100 with higher scores associated with better health states.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.2.2 (cont.): Subgroup MMRM for EQ-5D: VAS [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
ISS Stage at Study Entry:									0.6162
I-II	47	65.4 (19.3)	1.1 (2.0)	42	72.1 (19.2)	-4.1 (2.3)	5.1 (-0.9, 11.1) 0.0940	0.35 (-0.07, 0.77)	
III	5	70.0 (15.8)	1.5 (6.1)	6	47.3 (22.1)	1.2 (6.7)	0.3 (-17.7, 18.3) 0.9733	0.02 (-1.17, 1.21)	
Baseline LDH:									0.7412
<300IU/L	39	66.9 (19.7)	2.4 (2.1)	38	69.9 (21.2)	-1.4 (2.4)	3.8 (-2.6, 10.2) 0.2444	0.26 (-0.19, 0.71)	
>=300IU/L	11	61.2 (17.7)	-4.4 (4.1)	10	65.4 (20.9)	-10.4 (4.3)	6.0 (-5.8, 17.7) 0.3160	0.42 (-0.45, 1.28)	
Baseline Creatinine Clearance (ml/min):									0.8330
<60	11	62.5 (19.4)	-2.8 (4.0)	14	62.4 (25.3)	-6.2 (4.0)	3.4 (-7.8, 14.6) 0.5507	0.23 (-0.56, 1.02)	
>=60	40	66.7 (19.2)	2.2 (2.2)	34	71.7 (18.8)	-2.6 (2.5)	4.7 (-1.8, 11.3) 0.1549	0.33 (-0.13, 0.79)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The EQ-5D VAS score ranges from 0-100 with higher scores associated with better health states.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.2.2 (cont.): Subgroup MMRM for EQ-5D: VAS [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Number of Lines of Prior Therapy:									0.8185
2-3	30	66.1 (19.5)	-0.5 (2.4)	31	72.5 (21.3)	-4.5 (2.6)	3.9 (-3.1, 11.0) 0.2693	0.28 (-0.23, 0.78)	
>=4	22	65.5 (18.4)	3.4 (2.8)	17	62.5 (19.6)	-1.9 (3.4)	5.2 (-3.6, 14.0) 0.2408	0.37 (-0.27, 1.01)	
Region:									0.0047
North America	2	N.M.E.	N.M.E.	5	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Europe	37	67.2 (18.2)	0.7 (2.2)	37	67.8 (20.7)	-0.4 (2.5)	1.1 (-5.6, 7.8) 0.7420	0.07 (-0.38, 0.53)	
Japan	13	59.0 (20.2)	3.8 (3.6)	6	63.0 (25.1)	-18.2 (5.4)	22.0 (9.2, 34.8) 0.0010	1.59 (0.50, 2.68)	
ROW	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Baseline ECOG Performance Status I:									0.7236
0-1	49	65.8 (19.3)	1.4 (1.8)	42	70.9 (19.4)	-1.9 (2.2)	3.4 (-2.3, 9.0) 0.2434	0.24 (-0.17, 0.65)	
2	3	66.7 (11.5)	-7.9 (8.5)	6	55.7 (28.6)	-14.9 (5.5)	7.1 (-13.1, 27.2) 0.4885	0.43 (-0.97, 1.83)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The EQ-5D VAS score ranges from 0-100 with higher scores associated with better health states.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.2.2 (cont.): Subgroup MMRM for EQ-5D: VAS [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Baseline ECOG Performance Status II:									0.2361
0	26	68.9 (19.3)	6.1 (2.6)	20	73.5 (14.4)	-1.2 (3.3)	7.4 (-1.0, 15.7) 0.0829	0.51 (-0.09, 1.10)	
>=1	26	62.8 (18.3)	-4.4 (2.7)	28	65.8 (24.4)	-5.4 (2.7)	1.0 (-6.6, 8.6) 0.8003	0.07 (-0.47, 0.60)	
Prior Stem Cell Transplant:									0.7755
Yes	26	67.2 (20.7)	2.5 (2.6)	28	69.0 (21.9)	-1.8 (2.7)	4.3 (-3.2, 11.7) 0.2602	0.30 (-0.24, 0.84)	
No	26	64.5 (17.2)	-0.3 (2.6)	20	69.0 (20.3)	-6.2 (3.2)	5.8 (-2.5, 14.1) 0.1664	0.40 (-0.19, 0.99)	
Myeloma Risk Category:									0.7750
High Risk	5	77.2 (3.6)	10.0 (6.3)	9	61.1 (24.3)	2.1 (4.9)	7.9 (-8.0, 23.9) 0.3277	0.51 (-0.60, 1.62)	
Low Risk	2	N.M.E.	N.M.E.	1	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Standard Risk	40	63.8 (19.1)	1.6 (2.1)	35	71.9 (18.3)	-3.9 (2.4)	5.4 (-1.0, 11.9) 0.0967	0.38 (-0.08, 0.84)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The EQ-5D VAS score ranges from 0-100 with higher scores associated with better health states.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.2.2 (cont.): Subgroup MMRM for EQ-5D: VAS [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Individual Fish Abnormality (t(4;14)):									0.2866
Yes	7	70.6 (23.7)	13.9 (5.1)	9	68.9 (23.8)	0.1 (5.0)	13.8 (-0.4, 27.9) 0.0562	0.91 (-0.13, 1.95)	
No	37	63.1 (17.8)	1.0 (2.2)	31	67.8 (19.1)	-4.5 (2.6)	5.4 (-1.4, 12.3) 0.1151	0.38 (-0.10, 0.86)	
Individual Fish Abnormality (1Q21):									0.8571
Yes	22	68.7 (18.8)	5.1 (3.1)	25	68.3 (22.5)	-2.1 (3.2)	7.2 (-1.6, 15.9) 0.1075	0.46 (-0.12, 1.04)	
No	22	59.5 (17.9)	-0.3 (3.1)	13	69.6 (14.4)	-6.3 (4.0)	6.0 (-4.1, 16.1) 0.2428	0.40 (-0.30, 1.09)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The EQ-5D VAS score ranges from 0-100 with higher scores associated with better health states.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Subgruppenergebnisse für den Endpunkt Gesundheitszustand gemessen anhand des MDASI-MM

Table 5.1.1: Subgroup MMRM for MDASI-MM: Core Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
MDASI-MM: Core Symptom Severity									
All Patients	47	1.7 (1.5)	0.5 (0.2)	40	1.7 (1.5)	0.4 (0.3)	0.1 (-0.5, 0.6) 0.8285	0.05 (-0.38, 0.47)	
Age Category I:									0.1988
<75 years	36	1.7 (1.5)	0.4 (0.2)	30	1.5 (1.4)	0.5 (0.2)	-0.1 (-0.7, 0.5) 0.7344	-0.08 (-0.57, 0.40)	
>=75 years	11	1.7 (1.4)	0.1 (0.3)	10	2.6 (1.6)	-0.5 (0.4)	0.6 (-0.4, 1.6) 0.2449	0.48 (-0.38, 1.35)	
Age Category II:									0.9715
<65 years	15	1.4 (1.6)	0.3 (0.3)	14	1.7 (1.3)	0.3 (0.3)	0.1 (-0.8, 0.9) 0.9045	0.04 (-0.69, 0.77)	
>=65 years	32	1.9 (1.4)	0.3 (0.2)	26	1.7 (1.6)	0.2 (0.3)	0.1 (-0.6, 0.8) 0.8399	0.05 (-0.47, 0.57)	
Age Category III:									0.3706
<65 years	15	1.4 (1.6)	0.3 (0.3)	14	1.7 (1.3)	0.3 (0.3)	0.1 (-0.8, 0.9) 0.8625	0.06 (-0.67, 0.79)	
>=65 - <75 years	21	2.0 (1.5)	0.4 (0.2)	16	1.2 (1.4)	0.6 (0.3)	-0.3 (-1.1, 0.5) 0.4871	-0.22 (-0.88, 0.43)	
>=75 years	11	1.7 (1.4)	0.1 (0.3)	10	2.6 (1.6)	-0.5 (0.4)	0.6 (-0.4, 1.6) 0.2615	0.47 (-0.40, 1.34)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.1 (cont.): Subgroup MMRM for MDASI-MM: Core Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Race :									0.5154
White	33	1.7 (1.6)	0.4 (0.2)	30	1.7 (1.5)	0.2 (0.3)	0.2 (-0.4, 0.9) 0.5318	0.15 (-0.34, 0.65)	
Black or African American	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Asian	14	1.7 (1.3)	0.3 (0.3)	8	1.7 (1.4)	0.4 (0.4)	-0.1 (-1.1, 0.8) 0.7868	-0.11 (-0.98, 0.76)	
Other	0	N.M.E.	N.M.E.	2	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Gender:									0.9717
Male	26	1.8 (1.6)	0.3 (0.2)	24	1.5 (1.2)	0.2 (0.3)	0.1 (-0.7, 0.8) 0.8814	0.04 (-0.51, 0.60)	
Female	21	1.7 (1.3)	0.3 (0.2)	16	2.1 (1.8)	0.3 (0.3)	0.1 (-0.7, 0.9) 0.8624	0.06 (-0.59, 0.71)	
Baseline B2 Microglobulin (mg/L):									0.5960
<3.5	27	1.9 (1.7)	0.3 (0.2)	25	1.4 (1.2)	0.3 (0.3)	-0.0 (-0.7, 0.7) 0.9066	-0.03 (-0.58, 0.51)	
>=3.5	19	1.4 (1.2)	0.3 (0.3)	15	2.4 (1.7)	0.1 (0.3)	0.2 (-0.6, 1.1) 0.6051	0.17 (-0.51, 0.85)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.1 (cont.): Subgroup MMRM for MDASI-MM: Core Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
ISS Stage at Study Entry:									0.8975
I-II	42	1.7 (1.5)	0.3 (0.2)	35	1.7 (1.5)	0.2 (0.2)	0.0 (-0.6, 0.6) 0.8734	0.04 (-0.41, 0.48)	
III	5	1.5 (1.8)	0.7 (0.5)	5	1.9 (1.3)	0.6 (0.5)	0.1 (-1.3, 1.6) 0.8416	0.11 (-1.13, 1.35)	
Baseline LDH:									0.5436
<300IU/L	36	1.5 (1.4)	0.2 (0.2)	32	1.7 (1.5)	0.2 (0.2)	0.0 (-0.6, 0.6) 0.9981	0.00 (-0.48, 0.48)	
>=300IU/L	8	2.4 (1.6)	0.9 (0.4)	8	1.8 (1.5)	0.6 (0.4)	0.4 (-0.7, 1.4) 0.5262	0.30 (-0.69, 1.28)	
Baseline Creatinine Clearance (ml/min):									0.1572
<60	11	2.1 (1.4)	0.4 (0.3)	13	2.8 (1.5)	-0.2 (0.4)	0.6 (-0.3, 1.6) 0.2082	0.50 (-0.32, 1.31)	
>=60	35	1.6 (1.5)	0.3 (0.2)	27	1.2 (1.2)	0.4 (0.3)	-0.1 (-0.8, 0.5) 0.6744	-0.11 (-0.61, 0.40)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.1 (cont.): Subgroup MMRM for MDASI-MM: Core Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Number of Lines of Prior Therapy:									0.1385
2-3	26	1.7 (1.7)	0.5 (0.2)	26	1.8 (1.6)	0.1 (0.3)	0.3 (-0.3, 1.0) 0.3206	0.27 (-0.28, 0.81)	
>=4	21	1.7 (1.3)	0.1 (0.2)	14	1.7 (1.3)	0.4 (0.3)	-0.4 (-1.2, 0.4) 0.3694	-0.30 (-0.98, 0.38)	
Region:									0.1569
North America	1	N.M.E.	N.M.E.	5	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Europe	33	1.8 (1.6)	0.3 (0.2)	29	1.7 (1.5)	0.1 (0.3)	0.2 (-0.5, 0.9) 0.5396	0.15 (-0.35, 0.65)	
Japan	13	1.6 (1.3)	0.1 (0.3)	6	1.9 (1.6)	0.7 (0.5)	-0.6 (-1.7, 0.5) 0.2794	-0.51 (-1.49, 0.47)	
ROW	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Baseline ECOG Performance Status I:									0.9673
0-1	45	1.7 (1.5)	0.3 (0.2)	35	1.6 (1.5)	0.2 (0.2)	0.1 (-0.5, 0.7) 0.7194	0.08 (-0.36, 0.52)	
2	2	2.9 (0.6)	0.8 (0.8)	5	2.8 (0.7)	0.7 (0.5)	0.1 (-1.7, 2.0) 0.8767	0.11 (-1.53, 1.75)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.1 (cont.): Subgroup MMRM for MDASI-MM: Core Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Baseline ECOG Performance Status II:									0.4740
0	25	1.2 (1.3)	-0.1 (0.2)	20	1.1 (1.1)	-0.0 (0.3)	-0.0 (-0.8, 0.7) 0.8926	-0.04 (-0.63, 0.55)	
>=1	22	2.3 (1.4)	0.8 (0.2)	20	2.4 (1.5)	0.5 (0.3)	0.3 (-0.5, 1.0) 0.4727	0.22 (-0.39, 0.82)	
Prior Stem Cell Transplant:									0.7063
Yes	25	1.9 (1.6)	0.5 (0.2)	25	1.4 (1.2)	0.3 (0.3)	0.2 (-0.5, 0.9) 0.6163	0.14 (-0.42, 0.69)	
No	22	1.5 (1.4)	0.1 (0.2)	15	2.3 (1.7)	0.1 (0.3)	-0.0 (-0.8, 0.8) 0.9938	-0.00 (-0.66, 0.65)	
Myeloma Risk Category:									0.9519
High Risk	5	0.8 (0.4)	0.3 (0.5)	6	1.6 (1.4)	0.2 (0.4)	0.1 (-1.2, 1.4) 0.9223	0.05 (-1.13, 1.24)	
Low Risk	2	N.M.E.	N.M.E.	1	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Standard Risk	35	1.8 (1.5)	0.3 (0.2)	30	1.7 (1.5)	0.2 (0.2)	0.1 (-0.5, 0.7) 0.7400	0.08 (-0.41, 0.57)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.1 (cont.): Subgroup MMRM for MDASI-MM: Core Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Individual Fish Abnormality (t(4;14)):									0.7501
Yes	6	1.2 (1.3)	0.3 (0.4)	6	1.0 (1.2)	0.3 (0.5)	-0.0 (-1.3, 1.3) 0.9974	-0.00 (-1.13, 1.13)	
No	34	1.8 (1.5)	0.4 (0.2)	27	1.9 (1.5)	0.2 (0.3)	0.2 (-0.5, 0.9) 0.5282	0.16 (-0.35, 0.66)	
Individual Fish Abnormality (1Q21):									0.0779
Yes	18	1.4 (1.4)	0.2 (0.3)	20	1.7 (1.6)	0.4 (0.3)	-0.2 (-1.0, 0.6) 0.6039	-0.16 (-0.80, 0.47)	
No	22	2.0 (1.6)	0.5 (0.3)	11	1.6 (1.4)	-0.1 (0.4)	0.7 (-0.2, 1.5) 0.1253	0.55 (-0.19, 1.29)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.2: Subgroup MMRM for MDASI-MM: Module Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
MDASI-MM: Module Symptom Severity									
All Patients	46	1.2 (1.3)	0.8 (0.2)	40	1.4 (1.4)	0.6 (0.2)	0.1 (-0.4, 0.6) 0.5793	0.12 (-0.31, 0.54)	
Age Category I:									0.0490
<75 years	35	1.2 (1.3)	0.4 (0.2)	30	1.0 (1.2)	0.5 (0.2)	-0.1 (-0.6, 0.5) 0.7648	-0.07 (-0.56, 0.42)	
>=75 years	11	1.1 (1.1)	0.4 (0.3)	10	2.5 (1.4)	-0.5 (0.3)	0.9 (0.0, 1.8) 0.0474	0.83 (-0.06, 1.72)	
Age Category II:									0.4658
<65 years	15	1.1 (1.4)	0.1 (0.3)	14	1.3 (1.2)	0.2 (0.3)	-0.1 (-0.9, 0.7) 0.8172	-0.08 (-0.81, 0.65)	
>=65 years	31	1.3 (1.2)	0.5 (0.2)	26	1.4 (1.5)	0.3 (0.2)	0.2 (-0.4, 0.8) 0.4279	0.21 (-0.32, 0.73)	
Age Category III:									0.0563
<65 years	15	1.1 (1.4)	0.2 (0.2)	14	1.3 (1.2)	0.1 (0.3)	0.0 (-0.7, 0.8) 0.9067	0.04 (-0.69, 0.77)	
>=65 - <75 years	20	1.3 (1.3)	0.6 (0.2)	16	0.7 (1.0)	0.9 (0.3)	-0.3 (-0.9, 0.4) 0.4216	-0.26 (-0.92, 0.40)	
>=75 years	11	1.1 (1.1)	0.4 (0.3)	10	2.5 (1.4)	-0.6 (0.3)	1.0 (0.1, 1.9) 0.0227	0.96 (0.05, 1.86)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.2 (cont.): Subgroup MMRM for MDASI-MM: Module Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Race :									0.9501
White	32	1.1 (1.2)	0.4 (0.2)	30	1.3 (1.4)	0.4 (0.2)	0.1 (-0.5, 0.6) 0.8550	0.05 (-0.45, 0.54)	
Black or African American	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Asian	14	1.4 (1.4)	0.4 (0.3)	8	1.5 (1.5)	0.3 (0.4)	0.1 (-0.8, 1.0) 0.8523	0.08 (-0.79, 0.95)	
Other	0	N.M.E.	N.M.E.	2	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Gender:									0.2173
Male	26	1.3 (1.3)	0.6 (0.2)	24	1.3 (1.4)	0.3 (0.2)	0.4 (-0.3, 1.0) 0.2454	0.32 (-0.24, 0.88)	
Female	20	1.1 (1.3)	0.1 (0.2)	16	1.5 (1.4)	0.3 (0.3)	-0.2 (-0.9, 0.6) 0.6531	-0.15 (-0.80, 0.51)	
Baseline B2 Microglobulin (mg/L):									0.8484
<3.5	27	1.4 (1.4)	0.4 (0.2)	25	1.1 (1.2)	0.2 (0.2)	0.2 (-0.4, 0.8) 0.6018	0.14 (-0.40, 0.69)	
>=3.5	19	0.9 (1.0)	0.5 (0.2)	15	1.9 (1.6)	0.4 (0.3)	0.1 (-0.7, 0.8) 0.8470	0.06 (-0.61, 0.74)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.2 (cont.): Subgroup MMRM for MDASI-MM: Module Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
ISS Stage at Study Entry:									0.1459
I-II	41	1.2 (1.2)	0.3 (0.2)	35	1.3 (1.3)	0.2 (0.2)	0.0 (-0.5, 0.6) 0.8944	0.03 (-0.42, 0.48)	
III	5	1.3 (1.7)	1.6 (0.4)	5	2.1 (2.1)	0.6 (0.5)	1.0 (-0.3, 2.3) 0.1208	0.88 (-0.42, 2.18)	
Baseline LDH:									0.3500
<300IU/L	36	1.1 (1.2)	0.4 (0.2)	32	1.3 (1.4)	0.4 (0.2)	-0.0 (-0.6, 0.6) 0.9900	-0.00 (-0.48, 0.47)	
>=300IU/L	7	1.8 (1.7)	0.3 (0.4)	8	1.7 (1.4)	-0.2 (0.4)	0.5 (-0.5, 1.6) 0.3238	0.48 (-0.55, 1.51)	
Baseline Creatinine Clearance (ml/min):									0.0827
<60	11	1.5 (1.3)	0.6 (0.3)	13	2.5 (1.6)	-0.2 (0.3)	0.8 (-0.1, 1.6) 0.0778	0.70 (-0.13, 1.52)	
>=60	34	1.1 (1.3)	0.4 (0.2)	27	0.8 (0.8)	0.5 (0.2)	-0.1 (-0.6, 0.5) 0.7687	-0.07 (-0.58, 0.43)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
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[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.2 (cont.): Subgroup MMRM for MDASI-MM: Module Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Number of Lines of Prior Therapy:									0.2225
2-3	26	1.4 (1.5)	0.5 (0.2)	26	1.4 (1.3)	0.2 (0.2)	0.3 (-0.2, 0.9) 0.2496	0.31 (-0.23, 0.86)	
>=4	20	1.0 (0.9)	0.3 (0.2)	14	1.4 (1.5)	0.5 (0.3)	-0.2 (-0.9, 0.5) 0.6059	-0.17 (-0.86, 0.51)	
Region:									0.9836
North America	1	N.M.E.	N.M.E.	5	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Europe	32	1.2 (1.2)	0.4 (0.2)	29	1.4 (1.4)	0.3 (0.2)	0.1 (-0.5, 0.7) 0.6644	0.11 (-0.39, 0.61)	
Japan	13	1.4 (1.5)	0.4 (0.3)	6	1.7 (1.6)	0.3 (0.4)	0.1 (-0.9, 1.1) 0.8171	0.11 (-0.86, 1.08)	
ROW	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Baseline ECOG Performance Status I:									0.9229
0-1	45	1.2 (1.3)	0.4 (0.2)	35	1.2 (1.2)	0.3 (0.2)	0.1 (-0.4, 0.7) 0.6153	0.11 (-0.33, 0.55)	
2	1	2.0 (N.A.)	0.5 (1.0)	5	2.9 (1.6)	0.3 (0.5)	0.2 (-2.0, 2.5) 0.8286	0.19 (-1.96, 2.34)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.2 (cont.): Subgroup MMRM for MDASI-MM: Module Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Baseline ECOG Performance Status II:									0.2859
0	25	0.8 (1.1)	0.3 (0.2)	20	0.8 (1.1)	0.3 (0.3)	-0.1 (-0.7, 0.6) 0.8249	-0.06 (-0.65, 0.52)	
>=1	21	1.7 (1.3)	0.6 (0.2)	20	1.9 (1.5)	0.2 (0.3)	0.4 (-0.3, 1.0) 0.2596	0.34 (-0.27, 0.96)	
Prior Stem Cell Transplant:									0.3532
Yes	24	1.3 (1.4)	0.3 (0.2)	25	1.1 (1.3)	0.4 (0.2)	-0.0 (-0.6, 0.6) 0.9321	-0.02 (-0.58, 0.54)	
No	22	1.1 (1.2)	0.5 (0.2)	15	1.8 (1.5)	0.1 (0.3)	0.4 (-0.3, 1.1) 0.2964	0.34 (-0.32, 1.00)	
Myeloma Risk Category:									0.8479
High Risk	5	0.3 (0.3)	0.4 (0.5)	6	1.9 (1.9)	0.4 (0.4)	0.1 (-1.1, 1.3) 0.8955	0.07 (-1.12, 1.26)	
Low Risk	2	N.M.E.	N.M.E.	1	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Standard Risk	35	1.2 (1.2)	0.4 (0.2)	30	1.3 (1.4)	0.2 (0.2)	0.2 (-0.3, 0.7) 0.4451	0.19 (-0.30, 0.67)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.2 (cont.): Subgroup MMRM for MDASI-MM: Module Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Individual Fish Abnormality (t(4;14)):									0.2718
Yes	6	0.6 (0.7)	0.1 (0.4)	6	1.2 (1.9)	0.5 (0.4)	-0.4 (-1.6, 0.8) 0.4799	-0.37 (-1.51, 0.77)	
No	33	1.3 (1.4)	0.5 (0.2)	27	1.5 (1.4)	0.2 (0.2)	0.3 (-0.3, 0.9) 0.3319	0.25 (-0.26, 0.76)	
Individual Fish Abnormality (1Q21):									0.2353
Yes	18	0.8 (1.1)	0.5 (0.2)	20	1.4 (1.6)	0.5 (0.2)	0.0 (-0.7, 0.7) 0.9481	0.02 (-0.62, 0.66)	
No	21	1.6 (1.4)	0.4 (0.2)	11	1.5 (1.4)	-0.2 (0.3)	0.6 (-0.2, 1.4) 0.1275	0.55 (-0.19, 1.29)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.3: Subgroup MMRM for MDASI-MM: Total Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
MDASI-MM: Total Symptom Severity									
All Patients	47	1.5 (1.4)	0.6 (0.2)	40	1.6 (1.4)	0.5 (0.2)	0.1 (-0.5, 0.6) 0.7987	0.05 (-0.37, 0.48)	
Age Category I:									0.0113
<75 years	36	1.5 (1.4)	0.3 (0.2)	30	1.3 (1.2)	0.5 (0.2)	-0.2 (-0.7, 0.3) 0.4198	-0.20 (-0.68, 0.29)	
>=75 years	11	1.5 (1.2)	0.5 (0.3)	10	2.5 (1.4)	-0.6 (0.3)	1.1 (0.2, 2.0) 0.0144	1.03 (0.12, 1.94)	
Age Category II:									0.7122
<65 years	15	1.3 (1.5)	0.2 (0.3)	14	1.6 (1.3)	0.2 (0.3)	-0.0 (-0.8, 0.7) 0.9005	-0.04 (-0.77, 0.68)	
>=65 years	32	1.7 (1.3)	0.4 (0.2)	26	1.6 (1.5)	0.3 (0.2)	0.1 (-0.5, 0.7) 0.7105	0.10 (-0.42, 0.61)	
Age Category III:									0.1707
<65 years	15	1.3 (1.5)	0.2 (0.2)	14	1.6 (1.3)	0.2 (0.3)	-0.0 (-0.7, 0.7) 0.9905	-0.00 (-0.73, 0.72)	
>=65 - <75 years	21	1.8 (1.4)	0.5 (0.2)	16	1.1 (1.2)	0.8 (0.3)	-0.3 (-1.0, 0.4) 0.4140	-0.26 (-0.92, 0.39)	
>=75 years	11	1.5 (1.2)	0.2 (0.3)	10	2.5 (1.4)	-0.5 (0.3)	0.7 (-0.2, 1.6) 0.1151	0.66 (-0.22, 1.54)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.3 (cont.): Subgroup MMRM for MDASI-MM: Total Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Race :									0.6436
White	33	1.5 (1.4)	0.4 (0.2)	30	1.5 (1.4)	0.3 (0.2)	0.1 (-0.5, 0.7) 0.6354	0.12 (-0.38, 0.61)	
Black or African American	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Asian	14	1.6 (1.3)	0.3 (0.3)	8	1.6 (1.4)	0.3 (0.4)	-0.1 (-1.0, 0.8) 0.8629	-0.07 (-0.94, 0.80)	
Other	0	N.M.E.	N.M.E.	2	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Gender:									0.9938
Male	26	1.6 (1.5)	0.4 (0.2)	24	1.4 (1.2)	0.3 (0.2)	0.1 (-0.6, 0.7) 0.8308	0.06 (-0.50, 0.61)	
Female	21	1.5 (1.3)	0.3 (0.2)	16	1.9 (1.6)	0.2 (0.3)	0.1 (-0.7, 0.8) 0.8430	0.06 (-0.59, 0.71)	
Baseline B2 Microglobulin (mg/L):									0.4104
<3.5	27	1.7 (1.5)	0.3 (0.2)	25	1.3 (1.2)	0.3 (0.2)	-0.1 (-0.7, 0.5) 0.7859	-0.07 (-0.62, 0.47)	
>=3.5	19	1.2 (1.1)	0.4 (0.2)	15	2.2 (1.5)	0.1 (0.3)	0.3 (-0.5, 1.1) 0.4668	0.24 (-0.44, 0.92)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.3 (cont.): Subgroup MMRM for MDASI-MM: Total Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
ISS Stage at Study Entry:									0.4634
I-II	42	1.6 (1.4)	0.2 (0.2)	35	1.6 (1.4)	0.2 (0.2)	0.0 (-0.5, 0.6) 0.9585	0.01 (-0.44, 0.46)	
III	5	1.4 (1.7)	1.1 (0.4)	5	2.0 (1.6)	0.6 (0.5)	0.5 (-0.8, 1.8) 0.4381	0.44 (-0.81, 1.69)	
Baseline LDH:									0.5510
<300IU/L	36	1.4 (1.3)	0.3 (0.2)	32	1.6 (1.4)	0.3 (0.2)	0.0 (-0.6, 0.6) 0.9929	0.00 (-0.47, 0.48)	
>=300IU/L	8	2.2 (1.5)	0.7 (0.4)	8	1.7 (1.4)	0.4 (0.4)	0.3 (-0.7, 1.4) 0.5280	0.30 (-0.69, 1.28)	
Baseline Creatinine Clearance (ml/min):									0.0313
<60	11	1.9 (1.3)	0.5 (0.3)	13	2.7 (1.4)	-0.3 (0.3)	0.8 (-0.0, 1.7) 0.0615	0.74 (-0.09, 1.57)	
>=60	35	1.5 (1.4)	0.3 (0.2)	27	1.1 (1.0)	0.5 (0.2)	-0.2 (-0.8, 0.4) 0.4730	-0.18 (-0.68, 0.32)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.3 (cont.): Subgroup MMRM for MDASI-MM: Total Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Number of Lines of Prior Therapy:									0.1334
2-3	26	1.6 (1.6)	0.5 (0.2)	26	1.6 (1.4)	0.2 (0.2)	0.3 (-0.3, 0.9) 0.2994	0.28 (-0.27, 0.83)	
>=4	21	1.4 (1.1)	0.2 (0.2)	14	1.6 (1.3)	0.5 (0.3)	-0.3 (-1.1, 0.4) 0.3773	-0.30 (-0.98, 0.38)	
Region:									0.4041
North America	1	N.M.E.	N.M.E.	5	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Europe	33	1.6 (1.4)	0.4 (0.2)	29	1.6 (1.4)	0.2 (0.2)	0.1 (-0.5, 0.8) 0.6689	0.11 (-0.39, 0.61)	
Japan	13	1.5 (1.4)	0.2 (0.3)	6	1.9 (1.6)	0.5 (0.4)	-0.3 (-1.4, 0.7) 0.5366	-0.29 (-1.26, 0.68)	
ROW	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Baseline ECOG Performance Status I:									0.6942
0-1	45	1.5 (1.4)	0.3 (0.2)	35	1.4 (1.3)	0.2 (0.2)	0.1 (-0.5, 0.6) 0.7754	0.06 (-0.38, 0.50)	
2	2	2.5 (0.3)	0.9 (0.7)	5	2.8 (1.0)	0.5 (0.5)	0.4 (-1.3, 2.1) 0.6244	0.34 (-1.31, 1.99)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.3 (cont.): Subgroup MMRM for MDASI-MM: Total Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Baseline ECOG Performance Status II:									0.1385
0	25	1.0 (1.2)	0.0 (0.2)	20	1.0 (1.1)	0.2 (0.3)	-0.2 (-0.9, 0.4) 0.5284	-0.18 (-0.77, 0.41)	
>=1	22	2.1 (1.3)	0.7 (0.2)	20	2.2 (1.4)	0.3 (0.3)	0.4 (-0.3, 1.1) 0.2382	0.36 (-0.25, 0.97)	
Prior Stem Cell Transplant:									0.9582
Yes	25	1.7 (1.5)	0.4 (0.2)	25	1.3 (1.2)	0.3 (0.2)	0.1 (-0.6, 0.7) 0.7876	0.07 (-0.48, 0.63)	
No	22	1.4 (1.3)	0.3 (0.2)	15	2.1 (1.5)	0.1 (0.3)	0.1 (-0.6, 0.9) 0.7722	0.09 (-0.56, 0.75)	
Myeloma Risk Category:									0.9930
High Risk	5	0.6 (0.3)	0.4 (0.4)	6	1.7 (1.6)	0.3 (0.4)	0.1 (-1.1, 1.3) 0.8588	0.10 (-1.09, 1.28)	
Low Risk	2	N.M.E.	N.M.E.	1	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Standard Risk	35	1.6 (1.4)	0.3 (0.2)	30	1.5 (1.4)	0.2 (0.2)	0.1 (-0.5, 0.7) 0.7052	0.09 (-0.40, 0.58)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.3 (cont.): Subgroup MMRM for MDASI-MM: Total Symptom Severity [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Individual Fish Abnormality (t(4;14)):									0.3981
Yes	6	1.0 (1.1)	0.1 (0.4)	6	1.1 (1.5)	0.4 (0.5)	-0.3 (-1.5, 1.0) 0.6558	-0.23 (-1.37, 0.90)	
No	34	1.6 (1.5)	0.5 (0.2)	27	1.8 (1.4)	0.2 (0.2)	0.3 (-0.3, 0.9) 0.2911	0.27 (-0.24, 0.77)	
Individual Fish Abnormality (1Q21):									0.4717
Yes	18	1.2 (1.3)	0.5 (0.3)	20	1.6 (1.5)	0.1 (0.3)	0.4 (-0.4, 1.1) 0.3099	0.32 (-0.32, 0.96)	
No	22	1.8 (1.5)	0.4 (0.2)	11	1.5 (1.3)	0.4 (0.3)	-0.0 (-0.8, 0.8) 0.9631	-0.02 (-0.74, 0.71)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Subgruppenergebnisse für den Endpunkt Gesundheitsbezogene Lebensqualität gemessen anhand des MDASI-MM

Table 5.1.4: Subgroup MMRM for MDASI-MM: Symptom Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
MDASI-MM: Symptom Interference									
All Patients	46	2.5 (2.7)	0.7 (0.3)	40	2.1 (2.0)	1.0 (0.4)	-0.3 (-1.1, 0.5) 0.4451	-0.16 (-0.59, 0.26)	
Age Category I:									0.2213
<75 years	35	2.3 (2.7)	0.5 (0.3)	30	1.9 (2.1)	1.1 (0.3)	-0.6 (-1.4, 0.3) 0.2030	-0.31 (-0.80, 0.18)	
>=75 years	11	2.8 (2.9)	0.8 (0.5)	10	2.8 (1.8)	0.3 (0.6)	0.6 (-1.0, 2.1) 0.4883	0.29 (-0.57, 1.15)	
Age Category II:									0.7949
<65 years	15	2.3 (2.7)	0.4 (0.5)	14	2.4 (2.2)	0.8 (0.5)	-0.4 (-1.7, 0.9) 0.5057	-0.24 (-0.97, 0.49)	
>=65 years	31	2.5 (2.8)	0.7 (0.3)	26	2.0 (1.9)	1.0 (0.4)	-0.2 (-1.2, 0.7) 0.6355	-0.12 (-0.64, 0.40)	
Age Category III:									0.4409
<65 years	15	2.3 (2.7)	0.4 (0.5)	14	2.4 (2.2)	0.8 (0.5)	-0.4 (-1.7, 0.9) 0.5575	-0.21 (-0.94, 0.52)	
>=65 - <75 years	20	2.4 (2.8)	0.7 (0.4)	16	1.5 (1.9)	1.4 (0.5)	-0.7 (-1.9, 0.5) 0.2283	-0.39 (-1.06, 0.27)	
>=75 years	11	2.8 (2.9)	0.8 (0.6)	10	2.8 (1.8)	0.3 (0.6)	0.6 (-1.0, 2.1) 0.4938	0.28 (-0.58, 1.15)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.4 (cont.): Subgroup MMRM for MDASI-MM: Symptom Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Race :									0.7330
White	32	2.4 (2.4)	0.8 (0.3)	30	2.0 (1.7)	1.0 (0.3)	-0.2 (-1.2, 0.7) 0.5947	-0.13 (-0.63, 0.37)	
Black or African American	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Asian	14	2.6 (3.4)	0.3 (0.5)	8	1.9 (2.5)	0.9 (0.6)	-0.5 (-2.1, 1.0) 0.4788	-0.30 (-1.17, 0.57)	
Other	0	N.M.E.	N.M.E.	2	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Gender:									0.0697
Male	26	2.5 (2.7)	0.3 (0.3)	24	1.6 (1.7)	1.2 (0.4)	-0.9 (-1.9, 0.1) 0.0779	-0.49 (-1.05, 0.07)	
Female	20	2.4 (2.8)	1.0 (0.4)	16	2.9 (2.2)	0.5 (0.5)	0.5 (-0.7, 1.8) 0.3693	0.29 (-0.37, 0.95)	
Baseline B2 Microglobulin (mg/L):									0.5555
<3.5	27	2.5 (2.9)	0.6 (0.3)	25	1.7 (1.8)	1.0 (0.4)	-0.5 (-1.4, 0.5) 0.3497	-0.25 (-0.80, 0.29)	
>=3.5	19	2.3 (2.5)	0.6 (0.4)	15	2.9 (2.2)	0.6 (0.5)	0.0 (-1.3, 1.3) 0.9856	0.01 (-0.67, 0.68)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.4 (cont.): Subgroup MMRM for MDASI-MM: Symptom Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
ISS Stage at Study Entry:									0.0171
I-II	41	2.5 (2.8)	0.4 (0.3)	35	1.9 (1.8)	1.0 (0.3)	-0.6 (-1.4, 0.2) 0.1407	-0.33 (-0.79, 0.12)	
III	5	1.9 (1.7)	1.8 (0.7)	5	4.0 (2.5)	-0.5 (0.8)	2.3 (0.0, 4.5) 0.0455	1.14 (-0.19, 2.48)	
Baseline LDH:									0.2304
<300IU/L	36	2.0 (2.5)	0.7 (0.3)	32	1.9 (1.9)	0.8 (0.3)	-0.1 (-0.9, 0.8) 0.8322	-0.05 (-0.53, 0.43)	
>=300IU/L	7	5.0 (3.1)	0.1 (0.7)	8	3.0 (2.3)	1.4 (0.6)	-1.4 (-3.2, 0.5) 0.1561	-0.69 (-1.73, 0.36)	
Baseline Creatinine Clearance (ml/min):									0.0486
<60	11	2.6 (3.0)	1.1 (0.5)	13	3.6 (2.1)	0.1 (0.5)	1.0 (-0.5, 2.5) 0.1891	0.52 (-0.30, 1.33)	
>=60	34	2.5 (2.6)	0.5 (0.3)	27	1.5 (1.6)	1.3 (0.4)	-0.8 (-1.7, 0.1) 0.0972	-0.42 (-0.93, 0.09)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.4 (cont.): Subgroup MMRM for MDASI-MM: Symptom Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Number of Lines of Prior Therapy:									0.2866
2-3	26	3.0 (3.1)	0.8 (0.3)	26	2.1 (2.1)	0.7 (0.4)	0.0 (-1.0, 1.0) 0.9473	0.02 (-0.53, 0.56)	
>=4	20	1.8 (2.0)	0.4 (0.4)	14	2.3 (2.0)	1.2 (0.5)	-0.8 (-2.1, 0.4) 0.1876	-0.45 (-1.14, 0.25)	
Region:									0.5361
North America	1	N.M.E.	N.M.E.	5	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Europe	32	2.5 (2.4)	0.7 (0.3)	29	2.2 (1.9)	0.8 (0.4)	-0.1 (-1.1, 0.8) 0.8050	-0.06 (-0.56, 0.44)	
Japan	13	2.5 (3.5)	0.3 (0.5)	6	2.2 (2.8)	1.1 (0.8)	-0.8 (-2.6, 1.1) 0.3998	-0.39 (-1.37, 0.58)	
ROW	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Baseline ECOG Performance Status I:									0.4882
0-1	45	2.4 (2.7)	0.6 (0.3)	35	1.7 (1.7)	1.0 (0.3)	-0.4 (-1.2, 0.4) 0.3474	-0.21 (-0.65, 0.24)	
2	1	4.5 (N.A.)	1.4 (1.8)	5	4.9 (2.2)	0.4 (0.8)	1.0 (-2.8, 4.8) 0.6142	0.44 (-1.72, 2.60)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.4 (cont.): Subgroup MMRM for MDASI-MM: Symptom Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Baseline ECOG Performance Status II:									0.0326
0	25	1.7 (2.4)	0.0 (0.3)	20	1.4 (1.4)	1.0 (0.4)	-1.0 (-2.1, 0.0) 0.0587	-0.56 (-1.16, 0.04)	
>=1	21	3.3 (2.9)	1.4 (0.4)	20	2.9 (2.3)	0.8 (0.4)	0.6 (-0.5, 1.7) 0.2760	0.33 (-0.29, 0.95)	
Prior Stem Cell Transplant:									0.8029
Yes	24	2.6 (2.5)	0.5 (0.4)	25	2.0 (2.1)	0.8 (0.4)	-0.2 (-1.3, 0.8) 0.6319	-0.13 (-0.69, 0.43)	
No	22	2.3 (3.0)	0.7 (0.4)	15	2.4 (1.8)	1.2 (0.5)	-0.4 (-1.6, 0.8) 0.4605	-0.24 (-0.90, 0.42)	
Myeloma Risk Category:									0.1540
High Risk	5	2.1 (2.4)	-0.6 (0.7)	6	2.8 (2.4)	1.0 (0.7)	-1.6 (-3.6, 0.3) 0.1012	-0.90 (-2.15, 0.34)	
Low Risk	2	N.M.E.	N.M.E.	1	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Standard Risk	35	2.4 (2.7)	0.8 (0.3)	30	1.9 (1.9)	0.9 (0.3)	-0.1 (-1.0, 0.8) 0.7829	-0.07 (-0.55, 0.42)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.4 (cont.): Subgroup MMRM for MDASI-MM: Symptom Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Individual Fish Abnormality (t(4;14)):									0.0219
Yes	6	2.9 (4.2)	-0.9 (0.7)	6	2.0 (2.6)	1.5 (0.7)	-2.4 (-4.3, -0.5) 0.0142	-1.32 (-2.57, -0.07)	
No	33	2.6 (2.6)	0.9 (0.3)	27	2.1 (1.9)	0.9 (0.3)	0.0 (-0.8, 0.9) 0.9511	0.02 (-0.49, 0.52)	
Individual Fish Abnormality (1Q21):									0.9605
Yes	18	2.0 (2.3)	0.7 (0.4)	20	1.9 (1.9)	1.1 (0.4)	-0.4 (-1.5, 0.8) 0.5026	-0.21 (-0.85, 0.43)	
No	21	3.3 (3.1)	0.5 (0.4)	11	2.2 (2.4)	0.9 (0.5)	-0.3 (-1.6, 0.9) 0.5956	-0.19 (-0.92, 0.54)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.5: Subgroup MMRM for MDASI-MM: Activity Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
MDASI-MM: Activity Interference									
All Patients	46	2.5 (2.8)	0.9 (0.4)	40	2.8 (2.8)	1.1 (0.4)	-0.2 (-1.0, 0.7) 0.7037	-0.08 (-0.50, 0.34)	
Age Category I:									0.3977
<75 years	35	2.3 (2.7)	0.6 (0.3)	30	2.6 (2.9)	1.0 (0.4)	-0.4 (-1.4, 0.6) 0.4634	-0.18 (-0.67, 0.31)	
>=75 years	11	3.3 (3.3)	1.0 (0.6)	10	3.3 (2.3)	0.5 (0.7)	0.5 (-1.3, 2.3) 0.5768	0.23 (-0.63, 1.09)	
Age Category II:									0.6889
<65 years	15	2.3 (2.5)	0.4 (0.5)	14	3.4 (3.2)	0.8 (0.5)	-0.4 (-1.9, 1.1) 0.5862	-0.19 (-0.92, 0.54)	
>=65 years	31	2.6 (3.0)	0.9 (0.4)	26	2.4 (2.5)	0.9 (0.4)	-0.0 (-1.1, 1.0) 0.9420	-0.02 (-0.54, 0.50)	
Age Category III:									0.7079
<65 years	15	2.3 (2.5)	0.4 (0.5)	14	3.4 (3.2)	0.8 (0.5)	-0.4 (-1.9, 1.1) 0.6117	-0.18 (-0.91, 0.55)	
>=65 - <75 years	20	2.3 (2.8)	0.8 (0.4)	16	1.8 (2.5)	1.1 (0.5)	-0.4 (-1.7, 1.0) 0.5978	-0.17 (-0.83, 0.49)	
>=75 years	11	3.3 (3.3)	1.0 (0.6)	10	3.3 (2.3)	0.5 (0.7)	0.5 (-1.3, 2.3) 0.5900	0.22 (-0.64, 1.08)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.5 (cont.): Subgroup MMRM for MDASI-MM: Activity Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Race :									0.7899
White	32	2.5 (2.6)	0.9 (0.3)	30	2.5 (2.3)	1.0 (0.4)	-0.1 (-1.1, 1.0) 0.8949	-0.03 (-0.53, 0.47)	
Black or African American	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Asian	14	2.6 (3.3)	0.4 (0.5)	8	2.3 (3.0)	0.8 (0.7)	-0.3 (-2.1, 1.4) 0.6988	-0.16 (-1.03, 0.71)	
Other	0	N.M.E.	N.M.E.	2	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Gender:									0.1228
Male	26	2.6 (2.8)	0.5 (0.4)	24	1.9 (2.1)	1.2 (0.4)	-0.8 (-1.9, 0.4) 0.1945	-0.36 (-0.92, 0.20)	
Female	20	2.4 (2.9)	1.0 (0.4)	16	4.1 (3.1)	0.4 (0.5)	0.7 (-0.7, 2.1) 0.3349	0.31 (-0.35, 0.98)	
Baseline B2 Microglobulin (mg/L):									0.4948
<3.5	27	2.6 (3.1)	0.7 (0.4)	25	2.0 (2.2)	1.1 (0.4)	-0.4 (-1.5, 0.7) 0.5072	-0.18 (-0.72, 0.37)	
>=3.5	19	2.4 (2.5)	0.7 (0.5)	15	4.0 (3.2)	0.5 (0.6)	0.3 (-1.2, 1.7) 0.7258	0.12 (-0.56, 0.79)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.5 (cont.): Subgroup MMRM for MDASI-MM: Activity Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
ISS Stage at Study Entry:									0.0155
I-II	41	2.6 (2.9)	0.5 (0.3)	35	2.4 (2.5)	1.0 (0.3)	-0.5 (-1.4, 0.4) 0.2757	-0.25 (-0.70, 0.21)	
III	5	1.5 (1.3)	2.4 (0.8)	5	5.3 (3.3)	-0.4 (1.0)	2.8 (0.3, 5.3) 0.0300	1.24 (-0.11, 2.60)	
Baseline LDH:									0.1005
<300IU/L	36	2.1 (2.6)	0.8 (0.3)	32	2.4 (2.5)	0.7 (0.4)	0.1 (-0.8, 1.1) 0.7867	0.06 (-0.41, 0.54)	
>=300IU/L	7	5.0 (3.1)	-0.2 (0.8)	8	4.0 (3.6)	1.5 (0.7)	-1.7 (-3.8, 0.3) 0.0906	-0.82 (-1.88, 0.23)	
Baseline Creatinine Clearance (ml/min):									0.2045
<60	11	2.8 (3.3)	1.2 (0.6)	13	4.5 (2.5)	0.3 (0.6)	0.8 (-0.9, 2.5) 0.3465	0.37 (-0.44, 1.18)	
>=60	34	2.5 (2.7)	0.6 (0.3)	27	1.9 (2.5)	1.1 (0.4)	-0.5 (-1.5, 0.6) 0.3609	-0.23 (-0.74, 0.28)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.5 (cont.): Subgroup MMRM for MDASI-MM: Activity Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Number of Lines of Prior Therapy:									0.0685
2-3	26	3.0 (3.1)	1.1 (0.4)	26	2.6 (2.9)	0.6 (0.4)	0.5 (-0.6, 1.5) 0.3967	0.23 (-0.32, 0.77)	
>=4	20	1.9 (2.4)	0.2 (0.4)	14	3.0 (2.5)	1.4 (0.5)	-1.2 (-2.6, 0.2) 0.0943	-0.57 (-1.26, 0.13)	
Region:									0.3931
North America	1	N.M.E.	N.M.E.	5	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Europe	32	2.6 (2.6)	0.9 (0.4)	29	2.9 (2.6)	0.8 (0.4)	0.1 (-1.0, 1.2) 0.8318	0.05 (-0.45, 0.56)	
Japan	13	2.6 (3.5)	0.1 (0.6)	6	2.7 (3.4)	1.0 (0.8)	-0.9 (-3.0, 1.1) 0.3821	-0.41 (-1.38, 0.57)	
ROW	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Baseline ECOG Performance Status I:									0.4247
0-1	45	2.5 (2.8)	0.7 (0.3)	35	2.3 (2.4)	1.0 (0.4)	-0.3 (-1.2, 0.6) 0.5503	-0.13 (-0.57, 0.31)	
2	1	5.0 (N.A.)	1.7 (2.0)	5	6.3 (2.8)	0.1 (0.9)	1.5 (-2.8, 5.9) 0.4930	0.59 (-1.58, 2.77)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.5 (cont.): Subgroup MMRM for MDASI-MM: Activity Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Baseline ECOG Performance Status II:									0.0067
0	25	1.8 (2.4)	-0.1 (0.4)	20	1.7 (1.8)	1.1 (0.5)	-1.2 (-2.4, -0.0) 0.0458	-0.59 (-1.19, 0.01)	
>=1	21	3.4 (3.1)	1.8 (0.4)	20	3.8 (3.2)	0.7 (0.5)	1.1 (-0.1, 2.3) 0.0770	0.54 (-0.08, 1.16)	
Prior Stem Cell Transplant:									0.7135
Yes	24	2.6 (2.5)	0.5 (0.4)	25	2.7 (2.9)	0.8 (0.4)	-0.3 (-1.5, 0.8) 0.5548	-0.16 (-0.73, 0.40)	
No	22	2.4 (3.2)	0.9 (0.4)	15	2.9 (2.6)	1.0 (0.5)	-0.0 (-1.4, 1.3) 0.9857	-0.01 (-0.66, 0.65)	
Myeloma Risk Category:									0.1287
High Risk	5	2.1 (2.5)	-0.8 (0.8)	6	3.7 (3.0)	0.9 (0.8)	-1.7 (-3.8, 0.5) 0.1249	-0.85 (-2.08, 0.39)	
Low Risk	2	N.M.E.	N.M.E.	1	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Standard Risk	35	2.5 (2.9)	0.9 (0.3)	30	2.3 (2.4)	0.9 (0.4)	0.1 (-0.9, 1.1) 0.8817	0.04 (-0.45, 0.52)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.5 (cont.): Subgroup MMRM for MDASI-MM: Activity Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Individual Fish Abnormality (t(4;14)):									0.0103
Yes	6	2.8 (4.2)	-0.9 (0.7)	6	2.4 (3.2)	2.0 (0.8)	-2.9 (-5.1, -0.8) 0.0076	-1.44 (-2.71, -0.17)	
No	33	2.7 (2.7)	1.0 (0.3)	27	2.6 (2.5)	0.9 (0.4)	0.1 (-0.8, 1.1) 0.8043	0.06 (-0.45, 0.57)	
Individual Fish Abnormality (1Q21):									0.9121
Yes	18	2.1 (2.7)	0.8 (0.5)	20	2.4 (2.4)	1.1 (0.4)	-0.3 (-1.6, 1.0) 0.6175	-0.16 (-0.79, 0.48)	
No	21	3.4 (3.0)	0.5 (0.4)	11	2.5 (3.1)	1.0 (0.6)	-0.4 (-1.8, 1.0) 0.5526	-0.21 (-0.94, 0.52)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.6: Subgroup MMRM for MDASI-MM: Affective Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
MDASI-MM: Affective Interference									
All Patients	46	2.4 (2.8)	0.3 (0.3)	40	1.5 (1.6)	0.7 (0.4)	-0.4 (-1.2, 0.4) 0.3420	-0.20 (-0.63, 0.22)	
Age Category I:									0.1160
<75 years	35	2.4 (2.8)	0.4 (0.3)	30	1.3 (1.5)	1.1 (0.3)	-0.7 (-1.6, 0.1) 0.1026	-0.40 (-0.89, 0.09)	
>=75 years	11	2.4 (2.8)	0.9 (0.5)	10	2.3 (1.5)	0.3 (0.6)	0.6 (-0.9, 2.1) 0.3989	0.35 (-0.51, 1.21)	
Age Category II:									0.8707
<65 years	15	2.4 (2.9)	0.2 (0.4)	14	1.4 (1.5)	0.7 (0.5)	-0.5 (-1.8, 0.8) 0.4436	-0.27 (-1.01, 0.46)	
>=65 years	31	2.4 (2.8)	0.7 (0.3)	26	1.6 (1.6)	1.1 (0.4)	-0.4 (-1.3, 0.6) 0.4412	-0.20 (-0.72, 0.32)	
Age Category III:									0.2463
<65 years	15	2.4 (2.9)	0.2 (0.4)	14	1.4 (1.5)	0.7 (0.5)	-0.5 (-1.8, 0.8) 0.4264	-0.28 (-1.02, 0.45)	
>=65 - <75 years	20	2.4 (2.8)	0.6 (0.4)	16	1.2 (1.6)	1.5 (0.4)	-0.9 (-2.1, 0.2) 0.1096	-0.52 (-1.19, 0.15)	
>=75 years	11	2.4 (2.8)	0.9 (0.5)	10	2.3 (1.5)	0.3 (0.6)	0.6 (-0.9, 2.1) 0.4052	0.35 (-0.52, 1.21)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.6 (cont.): Subgroup MMRM for MDASI-MM: Affective Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Race :									0.7177
White	32	2.3 (2.5)	0.6 (0.3)	30	1.4 (1.4)	0.9 (0.3)	-0.4 (-1.3, 0.5) 0.4406	-0.19 (-0.69, 0.31)	
Black or African American	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Asian	14	2.5 (3.5)	0.4 (0.4)	8	1.4 (2.0)	1.1 (0.6)	-0.6 (-2.1, 0.8) 0.3765	-0.37 (-1.25, 0.50)	
Other	0	N.M.E.	N.M.E.	2	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Gender:									0.0262
Male	26	2.4 (2.8)	0.1 (0.3)	24	1.4 (1.5)	1.2 (0.4)	-1.1 (-2.1, -0.1) 0.0292	-0.61 (-1.18, -0.04)	
Female	20	2.4 (2.8)	1.1 (0.4)	16	1.8 (1.8)	0.5 (0.4)	0.5 (-0.6, 1.7) 0.3492	0.30 (-0.36, 0.97)	
Baseline B2 Microglobulin (mg/L):									0.9553
<3.5	27	2.5 (2.9)	0.6 (0.3)	25	1.3 (1.5)	0.9 (0.4)	-0.4 (-1.3, 0.6) 0.4366	-0.21 (-0.76, 0.33)	
>=3.5	19	2.3 (2.6)	0.5 (0.4)	15	1.9 (1.7)	1.0 (0.5)	-0.4 (-1.6, 0.8) 0.4954	-0.23 (-0.91, 0.45)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.6 (cont.): Subgroup MMRM for MDASI-MM: Affective Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
ISS Stage at Study Entry:									0.0500
I-II	41	2.4 (2.9)	0.5 (0.3)	35	1.4 (1.5)	1.1 (0.3)	-0.6 (-1.5, 0.2) 0.1256	-0.35 (-0.80, 0.11)	
III	5	2.3 (2.3)	1.0 (0.7)	5	2.7 (2.0)	-0.6 (0.8)	1.6 (-0.5, 3.8) 0.1377	0.84 (-0.45, 2.14)	
Baseline LDH:									0.2571
<300IU/L	36	1.9 (2.5)	0.7 (0.3)	32	1.4 (1.6)	0.9 (0.3)	-0.2 (-1.0, 0.7) 0.6902	-0.09 (-0.57, 0.38)	
>=300IU/L	7	5.0 (3.2)	0.0 (0.7)	8	2.0 (1.5)	1.3 (0.6)	-1.3 (-3.2, 0.5) 0.1608	-0.68 (-1.72, 0.36)	
Baseline Creatinine Clearance (ml/min):									0.0792
<60	11	2.5 (3.2)	0.8 (0.5)	13	2.7 (1.7)	0.1 (0.5)	0.6 (-0.8, 2.0) 0.3627	0.36 (-0.45, 1.17)	
>=60	34	2.5 (2.7)	0.5 (0.3)	27	1.0 (1.2)	1.3 (0.4)	-0.8 (-1.7, 0.1) 0.0792	-0.45 (-0.96, 0.07)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.6 (cont.): Subgroup MMRM for MDASI-MM: Affective Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Number of Lines of Prior Therapy:									0.6106
2-3	26	2.9 (3.3)	0.7 (0.3)	26	1.5 (1.5)	0.9 (0.4)	-0.2 (-1.2, 0.7) 0.6367	-0.13 (-0.67, 0.42)	
>=4	20	1.7 (1.8)	0.4 (0.4)	14	1.5 (1.7)	1.0 (0.5)	-0.6 (-1.8, 0.6) 0.3061	-0.35 (-1.03, 0.34)	
Region:									0.3427
North America	1	N.M.E.	N.M.E.	5	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Europe	32	2.4 (2.4)	0.5 (0.3)	29	1.6 (1.5)	0.8 (0.4)	-0.2 (-1.1, 0.7) 0.6635	-0.11 (-0.61, 0.39)	
Japan	13	2.5 (3.6)	0.6 (0.4)	6	1.6 (2.3)	1.6 (0.7)	-1.1 (-2.7, 0.6) 0.1924	-0.61 (-1.59, 0.38)	
ROW	0	N.M.E.	N.M.E.	0	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Baseline ECOG Performance Status I:									0.6167
0-1	45	2.4 (2.8)	0.5 (0.3)	35	1.2 (1.3)	1.0 (0.3)	-0.5 (-1.3, 0.4) 0.2700	-0.24 (-0.69, 0.20)	
2	1	4.0 (N.A.)	1.1 (1.8)	5	3.6 (2.1)	0.6 (0.8)	0.5 (-3.3, 4.3) 0.7884	0.23 (-1.92, 2.38)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.6 (cont.): Subgroup MMRM for MDASI-MM: Affective Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Baseline ECOG Performance Status II:									0.4185
0	25	1.7 (2.5)	0.2 (0.3)	20	1.1 (1.2)	0.7 (0.4)	-0.5 (-1.4, 0.5) 0.3468	-0.27 (-0.87, 0.32)	
>=1	21	3.2 (2.9)	1.0 (0.4)	20	2.0 (1.8)	0.9 (0.4)	0.1 (-0.9, 1.1) 0.8444	0.06 (-0.55, 0.67)	
Prior Stem Cell Transplant:									0.3679
Yes	24	2.6 (2.7)	0.5 (0.3)	25	1.4 (1.6)	0.6 (0.4)	-0.2 (-1.2, 0.8) 0.7437	-0.09 (-0.65, 0.47)	
No	22	2.1 (3.0)	0.6 (0.3)	15	1.8 (1.6)	1.5 (0.5)	-0.8 (-2.0, 0.3) 0.1492	-0.47 (-1.14, 0.19)	
Myeloma Risk Category:									0.2740
High Risk	5	2.2 (2.4)	-0.4 (0.7)	6	1.8 (2.0)	0.9 (0.7)	-1.4 (-3.3, 0.6) 0.1653	-0.76 (-1.99, 0.47)	
Low Risk	2	N.M.E.	N.M.E.	1	N.M.E.	N.M.E.	N.M.E.	N.M.E.	
Standard Risk	35	2.3 (2.7)	0.7 (0.3)	30	1.5 (1.6)	0.9 (0.3)	-0.2 (-1.1, 0.7) 0.6240	-0.12 (-0.61, 0.37)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Table 5.1.6 (cont.): Subgroup MMRM for MDASI-MM: Affective Interference [All Randomized Population] (n=117)

	E-Pd			Pd			E-Pd versus Pd		
	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	N[1]	Values at Start of Study: Mean (SD)[2]	Change compared to Start of Study: LS Mean (SE)[3]	Difference in Mean Change [95% CI]: p-value[3]	SMD as Hedges' g [95% CI][4]	Test for subgroup and treat. int. p-value
Individual Fish Abnormality (t(4;14)):									0.2499
Yes	6	2.9 (4.1)	-0.5 (0.7)	6	1.6 (2.1)	0.9 (0.7)	-1.4 (-3.3, 0.6) 0.1607	-0.74 (-1.91, 0.43)	
No	33	2.5 (2.7)	0.8 (0.3)	27	1.6 (1.6)	0.9 (0.4)	-0.2 (-1.1, 0.8) 0.7242	-0.09 (-0.60, 0.42)	
Individual Fish Abnormality (1Q21):									0.8468
Yes	18	1.9 (2.3)	0.4 (0.4)	20	1.3 (1.5)	1.0 (0.4)	-0.5 (-1.7, 0.7) 0.3935	-0.27 (-0.91, 0.37)	
No	21	3.2 (3.3)	0.6 (0.4)	11	1.9 (1.9)	1.0 (0.5)	-0.3 (-1.7, 1.0) 0.6038	-0.19 (-0.92, 0.54)	

NOTE: Only the on-treatment common timepoints with 10 patients or more in both treatment groups are used in the analysis.
NOTE: The All Randomized population was defined as all enrolled subjects who were randomized.
NOTE: Subgroup analyses with less than 10 subjects in subgroups are not presented.
The MDASI-MM subscale scores range from 0 to 10 with higher scores meaning worse symptom severity.
[1] Number of patients in the analysis at the specific assessment timepoint used in the calculation of change compared to start of study.
[2] Mean and SD are based on observed values.
[3] Subgroup estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment, subgroup, timepoint, treatment*subgroup interaction, and treatment*timepoint interaction as fixed effects, baseline PRO score as covariate, and timepoint as a repeated measure. Models were run first using a UN, and then, if the model didn't converge, a CS, and finally a AR(1) covariance matrix.
[4] Hedges' g is calculated as the mean change in E-Pd minus the mean change in Pd divided by the pooled-standard deviation all multiplied by a correction factor (1-(3/(4*df-1))).
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Subgruppenergebnisse für den Endpunkt Verträglichkeit (inkl. Subgruppenergebnisse auf SOC/PT-Ebene)

Protocol: CA204125 Page 1 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
OVERALL	60	58 (96.7)	0.23 (0.10, 0.26)	55	53 (96.4)	0.10 (0.03, 0.26)	0.874 (0.602, 1.271) 0.5522	
AGE I								0.0477**
< 75	47	45 (95.7)	0.23 (0.10, 0.43)	43	42 (97.7)	0.07 (0.03, 0.20)	0.706 (0.461, 1.080) 0.1337	
>= 75	13	13 (100.0)	0.23 (0.03, 0.26)	12	11 (91.7)	0.34 (0.03, 0.69)	1.915 (0.826, 4.439) 0.1262	
AGE II								0.0185**
< 65	22	21 (95.5)	0.34 (0.03, 0.66)	21	21 (100.0)	0.07 (0.03, 0.10)	0.508 (0.269, 0.961) 0.0370	
>= 65	38	37 (97.4)	0.23 (0.10, 0.26)	34	32 (94.1)	0.26 (0.03, 0.43)	1.269 (0.784, 2.053) 0.2771	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:24

Protocol: CA204125 Page 2 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events / Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								0.0332**
< 65	22	21 (95.5)	0.34 (0.03, 0.66)	21	21 (100.0)	0.07 (0.03, 0.10)	0.508 (0.269, 0.961) 0.0370	
>= 65 AND < 75	25	24 (96.0)	0.23 (0.10, 0.26)	22	21 (95.5)	0.13 (0.03, 0.33)	1.023 (0.564, 1.854) 0.8341	
>= 75	13	13 (100.0)	0.23 (0.03, 0.26)	12	11 (91.7)	0.34 (0.03, 0.69)	1.915 (0.826, 4.439) 0.1262	
RACE								0.1151
WHITE	45	43 (95.6)	0.26 (0.10, 0.46)	45	43 (95.6)	0.10 (0.03, 0.26)	0.777 (0.508, 1.189) 0.3200	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	15 (100.0)	0.10 (0.03, 0.23)	8	8 (100.0)	0.13 (0.07, 0.69)	2.271 (0.806, 6.395) 0.1099	
OTHER	0	0	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 3 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Subgroups	E-Pd N	Patients with Event n (%)	KME [95%CI](mon) (1)	Pd N	Patients with Event n (%)	KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.0972
MALE	32	32 (100.0)	0.26 (0.16, 0.49)	34	34 (100.0)	0.10 (0.03, 0.26)	0.624 (0.380, 1.026) 0.0702	
FEMALE	28	26 (92.9)	0.10 (0.07, 0.23)	21	19 (90.5)	0.13 (0.03, 0.49)	1.217 (0.669, 2.213) 0.5055	
BASELINE B2 MICROGLOBULIN (MG/L)								0.0905
< 3.5	35	33 (94.3)	0.23 (0.07, 0.26)	31	31 (100.0)	0.10 (0.03, 0.26)	0.652 (0.393, 1.083) 0.0936	
>= 3.5	24	24 (100.0)	0.26 (0.07, 0.43)	24	22 (91.7)	0.16 (0.03, 0.49)	1.317 (0.714, 2.430) 0.3032	
NOT REPORTED	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 4 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Subgroups	E-Pd N	Patients with Event n (%)	KME [95%CI](mon) (1)	Pd N	Patients with Event n (%)	KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ISS STAGE AT STUDY ENTRY (CRF)								0.1778
I-II	53	51 (96.2)	0.23 (0.10, 0.26)	48	46 (95.8)	0.13 (0.03, 0.26)	0.938 (0.629, 1.399) 0.8209	
III	7	7 (100.0)	0.26 (0.03, 0.59)	7	7 (100.0)	0.03 (0.03, 0.26)	0.296 (0.083, 1.054) 0.0450	
BASELINE LDH								0.2742
< 300	43	43 (100.0)	0.20 (0.07, 0.26)	40	39 (97.5)	0.13 (0.03, 0.26)	1.002 (0.647, 1.553) 0.9287	
>= 300	14	12 (85.7)	0.26 (0.07, 0.66)	15	14 (93.3)	0.07 (0.03, 0.26)	0.647 (0.296, 1.413) 0.2760	
NOT REPORTED	3	3 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 5 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE CREATININE CLEARANCE (ML/MIN)								0.0270**
< 60	14	14 (100.0)	0.08 (0.03, 0.26)	16	15 (93.8)	0.26 (0.03, 0.62)	2.113 (0.957, 4.666) 0.0559	
>= 60	45	43 (95.6)	0.23 (0.10, 0.46)	39	38 (97.4)	0.07 (0.03, 0.26)	0.698 (0.449, 1.087) 0.1409	
NOT REPORTED	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NUMBER OF LINES OF PRIOR THERAPY (CRF)								0.4255
2-3	35	33 (94.3)	0.26 (0.10, 0.49)	35	34 (97.1)	0.13 (0.03, 0.33)	0.771 (0.476, 1.250) 0.3369	
>= 4	25	25 (100.0)	0.20 (0.03, 0.26)	20	19 (95.0)	0.10 (0.03, 0.26)	1.032 (0.563, 1.893) 0.8147	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:24

Protocol: CA204125 Page 6 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
REGION								0.1207
NORTH AMERICA	3	3 (100.0)	N.M.E.	6	6 (100.0)	N.M.E.	N.M.E.	
EUROPE	44	42 (95.5)	0.26 (0.07, 0.46)	43	41 (95.3)	0.10 (0.03, 0.26)	0.804 (0.521, 1.240) 0.4077	
JAPAN	13	13 (100.0)	0.10 (0.07, 0.23)	6	6 (100.0)	0.41 (0.10, 0.72)	3.492 (0.965, 12.632) 0.0470	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS I								0.9157
0-1	56	54 (96.4)	0.23 (0.10, 0.26)	47	45 (95.7)	0.10 (0.03, 0.26)	0.867 (0.583, 1.290) 0.5615	
2	4	4 (100.0)	0.36 (0.10, 0.59)	8	8 (100.0)	0.18 (0.03, 0.72)	1.086 (0.302, 3.909) 0.8890	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:24

Protocol: CA204125 Page 7 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS II								0.3567
0	28	28 (100.0)	0.23 (0.07, 0.46)	22	22 (100.0)	0.13 (0.03, 0.26)	0.654 (0.366, 1.168) 0.1695	
>= 1	32	30 (93.8)	0.25 (0.10, 0.26)	33	31 (93.9)	0.10 (0.03, 0.26)	1.014 (0.609, 1.689) 0.9036	
PRIOR STEM CELL TRANSPLANT								0.1032
YES	31	31 (100.0)	0.26 (0.10, 0.43)	32	31 (96.9)	0.07 (0.03, 0.13)	0.616 (0.369, 1.028) 0.0728	
NO	29	27 (93.1)	0.23 (0.07, 0.46)	23	22 (95.7)	0.43 (0.03, 0.69)	1.210 (0.685, 2.138) 0.4758	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:24

Protocol: CA204125 Page 8 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
MYELOMA RISK CATEGORY								0.8488
HIGH RISK	6	6 (100.0)	0.15 (0.07, 0.26)	10	10 (100.0)	0.03 (0.03, 0.26)	0.905 (0.303, 2.702) 0.9229	
LOW RISK	2	2 (100.0)	N.M.E.	1	1 (100.0)	N.M.E.	N.M.E.	
STANDARD RISK	46	44 (95.7)	0.23 (0.07, 0.46)	39	37 (94.9)	0.13 (0.03, 0.33)	0.965 (0.622, 1.496) 0.8976	
NOT EVALUABLE	6	6 (100.0)	0.34 (0.03, 2.69)	5	5 (100.0)	0.07 (0.03, 0.49)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	3 (100.0)	N.M.E.	6	6 (100.0)	N.M.E.	N.M.E.	
NO	47	47 (100.0)	N.M.E.	39	37 (94.9)	N.M.E.	N.M.E.	
NOT REPORTED	10	8 (80.0)	N.M.E.	10	10 (100.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:24

Protocol: CA204125 Page 9 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	7 (100.0)	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	
NO	44	44 (100.0)	N.M.E.	42	40 (95.2)	N.M.E.	N.M.E.	
NOT REPORTED	9	7 (77.8)	N.M.E.	11	11 (100.0)	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								0.4357
YES	7	7 (100.0)	0.07 (0.03, 0.66)	9	9 (100.0)	0.10 (0.03, 0.43)	0.791 (0.276, 2.264) 0.6554	
NO	43	43 (100.0)	0.23 (0.10, 0.26)	35	33 (94.3)	0.10 (0.03, 0.26)	1.156 (0.726, 1.840) 0.4651	
NOT REPORTED	10	8 (80.0)	0.84 (0.03, 2.69)	11	11 (100.0)	0.26 (0.03, 0.33)	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:24

Protocol: CA204125 Page 10 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								0.6528
YES	28	28 (100.0)	0.25 (0.07, 0.26)	29	27 (93.1)	0.10 (0.03, 0.43)	1.026 (0.602, 1.749) 0.8256	
NO	22	22 (100.0)	0.13 (0.03, 0.23)	13	13 (100.0)	0.13 (0.03, 0.26)	1.363 (0.650, 2.856) 0.3900	
NOT REPORTED	10	8 (80.0)	0.84 (0.03, 2.69)	13	13 (100.0)	0.10 (0.03, 0.26)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	2 (100.0)	N.M.E.	1	1 (100.0)	N.M.E.	N.M.E.	
NO	47	47 (100.0)	N.M.E.	41	39 (95.1)	N.M.E.	N.M.E.	
NOT REPORTED	11	9 (81.8)	N.M.E.	13	13 (100.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:24

Protocol: CA204125 Page 1 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	43 (71.7)	3.19 (0.72, 10.12)	55	44 (80.0)	0.72 (0.69, 2.00)	0.626 (0.406, 0.965) 0.0345	
AGE I								0.2934
< 75	47	32 (68.1)	6.47 (0.79, 10.15)	43	35 (81.4)	1.18 (0.69, 3.25)	0.542 (0.330, 0.889) 0.0146	
>= 75	13	11 (84.6)	0.76 (0.49, 17.31)	12	9 (75.0)	0.71 (0.43, N.A.)	0.895 (0.354, 2.260) 0.8153	
AGE II								0.0578
< 65	22	14 (63.6)	10.12 (1.64, 40.05)	21	16 (76.2)	1.18 (0.49, 3.55)	0.298 (0.129, 0.689) 0.0028	
>= 65	38	29 (76.3)	0.99 (0.49, 6.47)	34	28 (82.4)	0.72 (0.69, 2.40)	0.873 (0.516, 1.478) 0.6273	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:38

Protocol: CA204125 Page 2 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								0.1623
< 65	22	14 (63.6)	10.12 (1.64, 40.05)	21	16 (76.2)	1.18 (0.49, 3.55)	0.298 (0.129, 0.689) 0.0028	
>= 65 AND < 75	25	18 (72.0)	1.54 (0.26, 7.16)	22	19 (86.4)	0.95 (0.69, 6.74)	0.860 (0.445, 1.662) 0.6577	
>= 75	13	11 (84.6)	0.76 (0.49, 17.31)	12	9 (75.0)	0.71 (0.43, N.A.)	0.895 (0.354, 2.260) 0.8153	
RACE								0.9866
WHITE	45	32 (71.1)	5.22 (1.22, 10.15)	45	34 (75.6)	1.41 (0.72, 3.32)	0.624 (0.378, 1.029) 0.0673	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	11 (73.3)	0.72 (0.23, 11.07)	8	8 (100.0)	0.71 (0.10, 2.40)	0.695 (0.276, 1.748) 0.4222	
OTHER	0	0	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:38

Protocol: CA204125 Page 3 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.4299
MALE	32	26 (81.3)	2.20 (0.59, 7.89)	34	27 (79.4)	0.72 (0.49, 2.40)	0.761 (0.439, 1.317) 0.3518	
FEMALE	28	17 (60.7)	9.20 (0.72, 24.11)	21	17 (81.0)	0.72 (0.62, 3.32)	0.513 (0.255, 1.033) 0.0565	
BASELINE B2 MICROGLOBULIN (MG/L)								0.8811
< 3.5	35	23 (65.7)	6.47 (0.76, 40.05)	31	25 (80.6)	1.64 (0.72, 4.07)	0.596 (0.335, 1.062) 0.0813	
>= 3.5	24	19 (79.2)	1.38 (0.26, 11.07)	24	19 (79.2)	0.67 (0.43, 2.40)	0.614 (0.306, 1.231) 0.1600	
NOT REPORTED	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 4 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ISS STAGE AT STUDY ENTRY (CRF)								0.6199
I-II	53	37 (69.8)	6.47 (0.79, 10.15)	48	37 (77.1)	1.18 (0.72, 3.25)	0.627 (0.392, 1.003) 0.0532	
III	7	6 (85.7)	0.26 (0.03, 5.22)	7	7 (100.0)	0.43 (0.03, 0.69)	0.612 (0.192, 1.948) 0.3823	
BASELINE LDH								0.9879
< 300	43	31 (72.1)	3.42 (0.72, 10.12)	40	33 (82.5)	0.72 (0.69, 2.40)	0.603 (0.363, 1.003) 0.0506	
>= 300	14	9 (64.3)	9.20 (0.53, N.A.)	15	11 (73.3)	0.72 (0.30, 14.00)	0.615 (0.247, 1.534) 0.3073	
NOT REPORTED	3	3 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:38

Protocol: CA204125 Page 5 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE CREATININE CLEARANCE (ML/MIN)								0.0029**
< 60	14	12 (85.7)	0.54 (0.23, 0.76)	16	12 (75.0)	0.72 (0.62, 4.07)	1.708 (0.760, 3.835) 0.1748	
>= 60	45	30 (66.7)	7.89 (2.17, 14.00)	39	32 (82.1)	1.18 (0.49, 2.40)	0.442 (0.262, 0.745) 0.0019	
NOT REPORTED	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NUMBER OF LINES OF PRIOR THERAPY (CRF)								0.0072**
2-3	35	22 (62.9)	7.89 (1.54, 24.11)	35	31 (88.6)	0.72 (0.62, 1.41)	0.384 (0.216, 0.685) 0.0009	
>= 4	25	21 (84.0)	0.79 (0.49, 6.47)	20	13 (65.0)	2.40 (0.49, 12.85)	1.257 (0.622, 2.539) 0.5230	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 6 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.7670
NORTH AMERICA	3	3 (100.0)	N.M.E.	6	5 (83.3)	N.M.E.	N.M.E.	
EUROPE	44	31 (70.5)	3.42 (0.79, 10.15)	43	33 (76.7)	1.18 (0.66, 3.25)	0.601 (0.362, 0.999) 0.0500	
JAPAN	13	9 (69.2)	0.72 (0.23, N.A.)	6	6 (100.0)	0.69 (0.10, 12.85)	0.593 (0.205, 1.713) 0.3533	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS I								0.8127
0-1	56	40 (71.4)	3.42 (0.79, 10.12)	47	37 (78.7)	1.18 (0.69, 3.25)	0.640 (0.404, 1.013) 0.0571	
2	4	3 (75.0)	0.56 (0.49, N.A.)	8	7 (87.5)	0.61 (0.03, 2.40)	0.782 (0.199, 3.081) 0.7372	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:38

Protocol: CA204125 Page 7 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS II								0.8456
0	28	21 (75.0)	4.94 (0.72, 14.00)	22	17 (77.3)	1.82 (0.43, 6.74)	0.662 (0.342, 1.279) 0.2198	
>= 1	32	22 (68.8)	2.56 (0.49, 11.07)	33	27 (81.8)	0.72 (0.66, 1.64)	0.617 (0.344, 1.107) 0.1071	
PRIOR STEM CELL TRANSPLANT								0.9741
YES	31	22 (71.0)	6.47 (1.22, 10.15)	32	25 (78.1)	1.64 (0.66, 3.55)	0.583 (0.322, 1.055) 0.0744	
NO	29	21 (72.4)	0.76 (0.49, 17.31)	23	19 (82.6)	0.72 (0.49, 1.41)	0.705 (0.368, 1.349) 0.2941	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:38

Protocol: CA204125 Page 8 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
MYELOMA RISK CATEGORY								0.8933
HIGH RISK	6	5 (83.3)	1.17 (0.20, N.A.)	10	9 (90.0)	0.95 (0.03, 2.40)	0.704 (0.216, 2.301) 0.5704	
LOW RISK	2	1 (50.0)	N.M.E.	1	1 (100.0)	N.M.E.	N.M.E.	
STANDARD RISK	46	33 (71.7)	5.22 (0.72, 10.15)	39	29 (74.4)	0.72 (0.69, 3.25)	0.684 (0.410, 1.141) 0.1558	
NOT EVALUABLE	6	4 (66.7)	0.61 (0.26, N.A.)	5	5 (100.0)	0.72 (0.03, 4.07)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	3 (100.0)	N.M.E.	6	5 (83.3)	N.M.E.	N.M.E.	
NO	47	35 (74.5)	N.M.E.	39	31 (79.5)	N.M.E.	N.M.E.	
NOT REPORTED	10	5 (50.0)	N.M.E.	10	8 (80.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 9 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	5 (71.4)	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	
NO	44	34 (77.3)	N.M.E.	42	33 (78.6)	N.M.E.	N.M.E.	
NOT REPORTED	9	4 (44.4)	N.M.E.	11	9 (81.8)	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								0.4520
YES	7	4 (57.1)	7.89 (0.72, N.A.)	9	8 (88.9)	2.00 (0.43, 6.74)	0.226 (0.048, 1.076) 0.0423	
NO	43	35 (81.4)	1.64 (0.59, 7.16)	35	27 (77.1)	0.72 (0.69, 1.64)	0.772 (0.459, 1.296) 0.3574	
NOT REPORTED	10	4 (40.0)	N.A. (0.26, N.A.)	11	9 (81.8)	1.18 (0.03, 18.60)	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 10 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								0.4910
YES	28	21 (75.0)	2.46 (0.72, 10.12)	29	23 (79.3)	0.72 (0.49, 2.40)	0.604 (0.326, 1.120) 0.1135	
NO	22	17 (77.3)	3.42 (0.53, 14.00)	13	10 (76.9)	1.64 (0.66, 14.00)	0.891 (0.399, 1.992) 0.7974	
NOT REPORTED	10	5 (50.0)	N.A. (0.26, N.A.)	13	11 (84.6)	0.72 (0.03, 4.07)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	2 (100.0)	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	35 (74.5)	N.M.E.	41	33 (80.5)	N.M.E.	N.M.E.	
NOT REPORTED	11	6 (54.5)	N.M.E.	13	11 (84.6)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	41 (68.3)	9.20 (3.35, 17.31)	55	29 (52.7)	7.23 (3.32, 40.25)	1.064 (0.653, 1.732) 0.8034	
AGE I								0.6326
< 75	47	32 (68.1)	9.76 (4.99, 18.63)	43	24 (55.8)	6.74 (3.55, 18.60)	0.975 (0.566, 1.680) 0.9267	
>= 75	13	9 (69.2)	6.05 (0.59, 28.58)	12	5 (41.7)	N.A. (0.53, N.A.)	1.269 (0.402, 4.009) 0.6819	
AGE II								0.1959
< 65	22	14 (63.6)	12.16 (3.35, 40.05)	21	11 (52.4)	4.17 (1.18, N.A.)	0.714 (0.310, 1.642) 0.4257	
>= 65	38	27 (71.1)	6.05 (2.04, 17.31)	34	18 (52.9)	7.23 (3.32, 40.25)	1.322 (0.717, 2.437) 0.3682	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:44

Protocol: CA204125 Page 2 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
AGE III								0.4325
< 65	22	14 (63.6)	12.16 (3.35, 40.05)	21	11 (52.4)	4.17 (1.18, N.A.)	0.714 (0.310, 1.642) 0.4257	
>= 65 AND < 75	25	18 (72.0)	9.76 (1.81, 18.63)	22	13 (59.1)	7.23 (2.33, 40.25)	1.239 (0.594, 2.587) 0.5694	
>= 75	13	9 (69.2)	6.05 (0.59, 28.58)	12	5 (41.7)	N.A. (0.53, N.A.)	1.269 (0.402, 4.009) 0.6819	
RACE								0.9994
WHITE	45	33 (73.3)	5.98 (2.17, 14.00)	45	24 (53.3)	7.23 (3.32, 40.25)	1.241 (0.724, 2.126) 0.4304	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	8 (53.3)	18.63 (6.05, 28.45)	8	3 (37.5)	N.A. (1.18, N.A.)	0.884 (0.219, 3.574) 0.8625	
OTHER	0	0	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 3 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.3555
MALE	32	24 (75.0)	6.14 (2.69, 14.00)	34	18 (52.9)	6.74 (2.33, 40.25)	1.260 (0.676, 2.349) 0.4671	
FEMALE	28	17 (60.7)	12.45 (2.17, 28.45)	21	11 (52.4)	7.23 (3.32, 18.60)	0.754 (0.331, 1.715) 0.5004	
BASELINE B2 MICROGLOBULIN (MG/L)								0.8209
< 3.5	35	21 (60.0)	15.21 (6.05, 21.22)	31	15 (48.4)	12.19 (4.17, 40.25)	1.039 (0.524, 2.059) 0.9128	
>= 3.5	24	19 (79.2)	3.52 (0.59, 9.20)	24	14 (58.3)	2.40 (0.66, N.A.)	1.010 (0.487, 2.097) 0.9740	
NOT REPORTED	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 4 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ISS STAGE AT STUDY ENTRY (CRF)								0.5155
I-II	53	35 (66.0)	12.45 (3.35, 18.63)	48	24 (50.0)	12.19 (4.07, 40.25)	1.114 (0.653, 1.903) 0.6895	
III	7	6 (85.7)	5.22 (0.26, 8.57)	7	5 (71.4)	1.31 (0.13, N.A.)	0.547 (0.142, 2.117) 0.3716	
BASELINE LDH								0.1490
< 300	43	31 (72.1)	9.76 (3.12, 18.63)	40	18 (45.0)	7.23 (4.14, N.A.)	1.217 (0.666, 2.222) 0.5208	
>= 300	14	8 (57.1)	12.16 (1.18, N.A.)	15	11 (73.3)	0.72 (0.43, 40.25)	0.538 (0.209, 1.384) 0.1912	
NOT REPORTED	3	2 (66.7)	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE CREATININE CLEARANCE (ML/MIN)								0.7686
< 60	14	12 (85.7)	1.92 (0.26, 12.45)	16	10 (62.5)	4.07 (1.05, N.A.)	1.320 (0.543, 3.208) 0.5445	
>= 60	45	29 (64.4)	12.16 (5.22, 19.94)	39	19 (48.7)	12.19 (3.55, 40.25)	1.057 (0.583, 1.917) 0.8526	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NUMBER OF LINES OF PRIOR THERAPY (CRF)								0.5572
2-3	35	23 (65.7)	8.57 (3.12, 19.94)	35	20 (57.1)	6.74 (3.32, 40.25)	0.980 (0.530, 1.809) 0.9482	
>= 4	25	18 (72.0)	12.16 (1.22, 17.31)	20	9 (45.0)	12.19 (2.40, N.A.)	1.189 (0.518, 2.733) 0.6837	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 6 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9232
NORTH AMERICA	3	3 (100.0)	N.M.E.	6	5 (83.3)	N.M.E.	N.M.E.	
EUROPE	44	32 (72.7)	5.98 (2.04, 14.00)	43	22 (51.2)	12.19 (2.43, 40.25)	1.302 (0.746, 2.272) 0.3513	
JAPAN	13	6 (46.2)	18.63 (9.76, 28.45)	6	2 (33.3)	N.A. (4.14, N.A.)	0.686 (0.125, 3.775) 0.6634	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS I								0.1286
0-1	56	37 (66.1)	12.16 (5.22, 18.63)	47	23 (48.9)	12.19 (4.07, 40.25)	1.108 (0.649, 1.891) 0.7060	
2	4	4 (100.0)	0.56 (0.23, 1.18)	8	6 (75.0)	1.49 (0.13, N.A.)	2.331 (0.570, 9.530) 0.2314	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 7 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS II								0.4733
0	28	22 (78.6)	12.16 (6.05, 19.94)	22	9 (40.9)	18.60 (4.07, N.A.)	1.154 (0.515, 2.585) 0.7283	
>= 1	32	19 (59.4)	5.22 (1.22, N.A.)	33	20 (60.6)	4.14 (1.18, 40.25)	0.958 (0.504, 1.821) 0.8965	
PRIOR STEM CELL TRANSPLANT								0.5912
YES	31	21 (67.7)	9.20 (1.41, 15.21)	32	18 (56.3)	6.74 (2.40, N.A.)	0.969 (0.510, 1.839) 0.9222	
NO	29	20 (69.0)	12.45 (2.69, 19.94)	23	11 (47.8)	12.19 (3.32, 40.25)	1.258 (0.581, 2.727) 0.5539	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:44

Protocol: CA204125 Page 8 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
MYELOMA RISK CATEGORY								0.3578
HIGH RISK	6	5 (83.3)	3.70 (0.20, N.A.)	10	4 (40.0)	N.A. (0.43, N.A.)	1.721 (0.427, 6.946) 0.4413	
LOW RISK	2	1 (50.0)	N.M.E.	1	1 (100.0)	N.M.E.	N.M.E.	
STANDARD RISK	46	29 (63.0)	14.00 (6.14, 19.94)	39	19 (48.7)	12.19 (4.14, 40.25)	1.015 (0.559, 1.842) 0.9628	
NOT EVALUABLE	6	6 (100.0)	0.48 (0.23, 2.69)	5	5 (100.0)	0.72 (0.13, 4.07)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	3 (100.0)	N.M.E.	6	3 (50.0)	N.M.E.	N.M.E.	
NO	47	32 (68.1)	N.M.E.	39	18 (46.2)	N.M.E.	N.M.E.	
NOT REPORTED	10	6 (60.0)	N.M.E.	10	8 (80.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	4 (57.1)	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
NO	44	32 (72.7)	N.M.E.	42	20 (47.6)	N.M.E.	N.M.E.	
NOT REPORTED	9	5 (55.6)	N.M.E.	11	8 (72.7)	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								0.2925
YES	7	4 (57.1)	9.20 (0.79, 21.22)	9	5 (55.6)	3.55 (0.79, N.A.)	0.357 (0.068, 1.862) 0.1974	
NO	43	31 (72.1)	9.76 (3.35, 17.31)	35	16 (45.7)	12.19 (4.14, 40.25)	1.373 (0.736, 2.562) 0.3172	
NOT REPORTED	10	6 (60.0)	2.83 (0.23, N.A.)	11	8 (72.7)	3.32 (0.26, 18.60)	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 10 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								0.7294
YES	28	20 (71.4)	6.05 (1.41, 15.21)	29	13 (44.8)	7.23 (3.32, N.A.)	1.341 (0.656, 2.744) 0.4213	
NO	22	15 (68.2)	14.00 (5.98, 19.94)	13	8 (61.5)	12.19 (2.33, 40.25)	0.998 (0.404, 2.465) 0.9959	
NOT REPORTED	10	6 (60.0)	2.83 (0.10, N.A.)	13	8 (61.5)	4.07 (0.59, 18.60)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	2 (100.0)	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	32 (68.1)	N.M.E.	41	21 (51.2)	N.M.E.	N.M.E.	
NOT REPORTED	11	7 (63.6)	N.M.E.	13	8 (61.5)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 1 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Leading to Discontinuation of Study Treatment Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	11 (18.3)	N.A. (N.A., N.A.)	55	12 (21.8)	N.A. (40.25, N.A.)	0.717 (0.314, 1.639) 0.4281	
AGE I								0.5401
< 75	47	7 (14.9)	N.A. (25.17, N.A.)	43	9 (20.9)	N.A. (40.25, N.A.)	0.610 (0.225, 1.654) 0.3264	
>= 75	13	4 (30.8)	N.A. (2.17, N.A.)	12	3 (25.0)	N.A. (2.99, N.A.)	1.207 (0.270, 5.400) 0.8051	
AGE II								0.0534
< 65	22	1 (4.5)	N.A. (N.A., N.A.)	21	5 (23.8)	N.A. (4.40, N.A.)	0.171 (0.020, 1.466) 0.0675	
>= 65	38	10 (26.3)	N.A. (25.17, N.A.)	34	7 (20.6)	N.A. (40.25, N.A.)	1.315 (0.476, 3.636) 0.5967	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:50

Protocol: CA204125 Page 2 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events Leading to Discontinuation of Study Treatment Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								0.1456
< 65	22	1 (4.5)	N.A. (N.A., N.A.)	21	5 (23.8)	N.A. (4.40, N.A.)	0.171 (0.020, 1.466) 0.0675	
>= 65 AND < 75	25	6 (24.0)	N.A. (11.37, N.A.)	22	4 (18.2)	N.A. (40.25, N.A.)	1.606 (0.401, 6.436) 0.4999	
>= 75	13	4 (30.8)	N.A. (2.17, N.A.)	12	3 (25.0)	N.A. (2.99, N.A.)	1.207 (0.270, 5.400) 0.8051	
RACE								0.5714
WHITE	45	8 (17.8)	N.A. (N.A., N.A.)	45	10 (22.2)	40.25 (40.25, N.A.)	0.718 (0.281, 1.832) 0.4856	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	3 (20.0)	N.A. (9.76, N.A.)	8	1 (12.5)	N.A. (4.40, N.A.)	1.046 (0.094, 11.641) 0.9705	
OTHER	0	0	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 3 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Leading to Discontinuation of Study Treatment Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8912
MALE	32	6 (18.8)	N.A. (N.A., N.A.)	34	8 (23.5)	40.25 (40.25, N.A.)	0.676 (0.234, 1.955) 0.4667	
FEMALE	28	5 (17.9)	N.A. (25.17, N.A.)	21	4 (19.0)	N.A. (N.A., N.A.)	0.778 (0.202, 2.992) 0.7138	
BASELINE B2 MICROGLOBULIN (MG/L)								0.0834
< 3.5	35	6 (17.1)	N.A. (25.17, N.A.)	31	3 (9.7)	N.A. (40.25, N.A.)	1.512 (0.371, 6.162) 0.5619	
>= 3.5	24	4 (16.7)	N.A. (N.A., N.A.)	24	9 (37.5)	10.38 (2.79, N.A.)	0.369 (0.113, 1.209) 0.0866	
NOT REPORTED	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 4 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Leading to Discontinuation of Study Treatment Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ISS STAGE AT STUDY ENTRY (CRF)								0.8070
I-II	53	8 (15.1)	N.A. (N.A., N.A.)	48	9 (18.8)	N.A. (40.25, N.A.)	0.666 (0.254, 1.749) 0.4063	
III	7	3 (42.9)	N.A. (0.26, N.A.)	7	3 (42.9)	N.A. (0.59, N.A.)	1.019 (0.205, 5.067) 0.9815	
BASELINE LDH								0.2817
< 300	43	7 (16.3)	N.A. (25.17, N.A.)	40	5 (12.5)	N.A. (N.A., N.A.)	1.010 (0.316, 3.230) 0.9867	
>= 300	14	3 (21.4)	N.A. (1.64, N.A.)	15	7 (46.7)	25.31 (0.66, 40.25)	0.489 (0.122, 1.960) 0.3025	
NOT REPORTED	3	1 (33.3)	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 5 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Leading to Discontinuation of Study Treatment Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE CREATININE CLEARANCE (ML/MIN)								0.6810
< 60	14	6 (42.9)	25.17 (1.64, N.A.)	16	6 (37.5)	N.A. (1.31, N.A.)	0.927 (0.283, 3.038) 0.8996	
>= 60	45	5 (11.1)	N.A. (N.A., N.A.)	39	6 (15.4)	N.A. (40.25, N.A.)	0.619 (0.186, 2.059) 0.4302	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NUMBER OF LINES OF PRIOR THERAPY (CRF)								0.5183
2-3	35	5 (14.3)	N.A. (25.17, N.A.)	35	8 (22.9)	40.25 (40.25, N.A.)	0.525 (0.170, 1.624) 0.2554	
>= 4	25	6 (24.0)	N.A. (N.A., N.A.)	20	4 (20.0)	N.A. (4.07, N.A.)	1.068 (0.299, 3.818) 0.9187	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 6 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Leading to Discontinuation of Study Treatment Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9932
NORTH AMERICA	3	1 (33.3)	N.M.E.	6	3 (50.0)	N.M.E.	N.M.E.	
EUROPE	44	8 (18.2)	N.A. (N.A., N.A.)	43	9 (20.9)	N.A. (40.25, N.A.)	0.778 (0.298, 2.032) 0.6069	
JAPAN	13	2 (15.4)	N.A. (9.76, N.A.)	6	0	N.A. (N.A., N.A.)	N.M.E. 0.5271	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS I								0.2039
0-1	56	9 (16.1)	N.A. (N.A., N.A.)	47	10 (21.3)	N.A. (40.25, N.A.)	0.634 (0.255, 1.576) 0.3230	
2	4	2 (50.0)	N.A. (0.89, N.A.)	8	2 (25.0)	N.A. (0.59, N.A.)	2.310 (0.320, 16.668) 0.3933	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 7 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events Leading to Discontinuation of Study Treatment Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS II								0.7149
0	28	3 (10.7)	N.A. (25.17, N.A.)	22	3 (13.6)	N.A. (N.A., N.A.)	0.493 (0.097, 2.507) 0.3847	
>= 1	32	8 (25.0)	N.A. (N.A., N.A.)	33	9 (27.3)	40.25 (10.38, 40.25)	0.990 (0.371, 2.640) 0.9836	
PRIOR STEM CELL TRANSPLANT								0.8929
YES	31	5 (16.1)	N.A. (N.A., N.A.)	32	7 (21.9)	N.A. (N.A., N.A.)	0.616 (0.194, 1.953) 0.4058	
NO	29	6 (20.7)	N.A. (25.17, N.A.)	23	5 (21.7)	40.25 (10.38, 40.25)	0.734 (0.217, 2.484) 0.6176	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:50

Protocol: CA204125 Page 8 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Leading to Discontinuation of Study Treatment Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
MYELOMA RISK CATEGORY								0.9910
HIGH RISK	6	0	N.A. (N.A., N.A.)	10	1 (10.0)	N.A. (2.99, N.A.)	N.M.E. 0.4292	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	10 (21.7)	N.A. (25.17, N.A.)	39	8 (20.5)	N.A. (40.25, N.A.)	0.956 (0.371, 2.465) 0.9267	
NOT EVALUABLE	6	1 (16.7)	N.A. (1.18, N.A.)	5	3 (60.0)	4.07 (0.59, N.A.)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
NO	47	9 (19.1)	N.M.E.	39	9 (23.1)	N.M.E.	N.M.E.	
NOT REPORTED	10	2 (20.0)	N.M.E.	10	3 (30.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:50

Protocol: CA204125 Page 9 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Leading to Discontinuation of Study Treatment Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	2 (28.6)	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
NO	44	8 (18.2)	N.M.E.	42	8 (19.0)	N.M.E.	N.M.E.	
NOT REPORTED	9	1 (11.1)	N.M.E.	11	3 (27.3)	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								0.9926
YES	7	0	N.A. (N.A., N.A.)	9	1 (11.1)	N.A. (2.99, N.A.)	N.M.E. 0.3173	
NO	43	10 (23.3)	N.A. (25.17, N.A.)	35	8 (22.9)	40.25 (N.A., N.A.)	0.910 (0.356, 2.327) 0.8444	
NOT REPORTED	10	1 (10.0)	N.A. (11.37, N.A.)	11	3 (27.3)	N.A. (0.72, N.A.)	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:50

Protocol: CA204125 Page 10 of 10

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Adverse Events Leading to Discontinuation of Study Treatment on Hazard Ratio
Excluding Progression Terms
All Treated Subjects

Adverse Events Leading to Discontinuation of Study Treatment Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								0.5186
YES	28	6 (21.4)	N.A. (N.A., N.A.)	29	6 (20.7)	N.A. (N.A., N.A.)	0.992 (0.320, 3.077) 0.9885	
NO	22	3 (13.6)	N.A. (25.17, N.A.)	13	3 (23.1)	40.25 (10.38, 40.25)	0.443 (0.085, 2.324) 0.3246	
NOT REPORTED	10	2 (20.0)	N.A. (3.78, N.A.)	13	3 (23.1)	N.A. (4.07, N.A.)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	9 (19.1)	N.M.E.	41	9 (22.0)	N.M.E.	N.M.E.	
NOT REPORTED	11	2 (18.2)	N.M.E.	13	3 (23.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, Includes events reported between first dose and 60 days after last dose of study therapy.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsub-ebr2453.sas 01APR2021:08:01:50

Protocol: CA204125 Page 1 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	14 (23.3)	38.54 (23.95, N.A.)	55	7 (12.7)	N.A. (30.26, N.A.)	1.587 (0.635, 3.967) 0.3184	
AGE I								0.9923
< 75	47	10 (21.3)	24.87 (23.49, N.A.)	43	7 (16.3)	N.A. (30.26, N.A.)	1.278 (0.483, 3.385) 0.6197	
>= 75	13	4 (30.8)	38.54 (4.53, 38.54)	12	0	N.A. (N.A., N.A.)	N.M.E. 0.1451	
AGE II								0.0661
< 65	22	4 (18.2)	N.A. (23.95, N.A.)	21	4 (19.0)	13.34 (13.34, N.A.)	0.653 (0.156, 2.728) 0.5552	
>= 65	38	10 (26.3)	27.60 (23.49, 38.54)	34	3 (8.8)	N.A. (30.26, N.A.)	3.663 (0.959, 13.985) 0.0447	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:15

Protocol: CA204125

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	4 (18.2)	N.M.E.	21	4 (19.0)	N.M.E.	N.M.E.	
>= 65 AND < 75	25	6 (24.0)	N.M.E.	22	3 (13.6)	N.M.E.	N.M.E.	
>= 75	13	4 (30.8)	N.M.E.	12	0	N.M.E.	N.M.E.	
RACE								0.5809
WHITE	45	8 (17.8)	38.54 (23.95, N.A.)	45	3 (6.7)	N.A. (30.26, N.A.)	2.450 (0.645, 9.301) 0.1737	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	6 (40.0)	24.87 (4.53, N.A.)	8	2 (25.0)	N.A. (2.99, N.A.)	1.325 (0.253, 6.947) 0.7387	
OTHER	0	0	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:15

Protocol: CA204125 Page 3 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.3200
MALE	32	6 (18.8)	27.60 (15.67, N.A.)	34	2 (5.9)	N.A. (N.A., N.A.)	2.654 (0.532, 13.244) 0.2161	
FEMALE	28	8 (28.6)	38.54 (23.49, 38.54)	21	5 (23.8)	30.26 (13.34, N.A.)	1.158 (0.367, 3.649) 0.8021	
BASELINE B2 MICROGLOBULIN (MG/L)								0.0717
< 3.5	35	11 (31.4)	24.87 (23.49, N.A.)	31	3 (9.7)	N.A. (N.A., N.A.)	2.852 (0.792, 10.268) 0.0937	
>= 3.5	24	3 (12.5)	38.54 (N.A., N.A.)	24	4 (16.7)	30.26 (N.A., N.A.)	0.494 (0.090, 2.700) 0.4045	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:15

Protocol: CA204125 Page 4 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ISS STAGE AT STUDY ENTRY (CRF)								0.9906
I-II	53	14 (26.4)	27.60 (23.95, N.A.)	48	5 (10.4)	N.A. (30.26, N.A.)	2.275 (0.813, 6.368) 0.1080	
III	7	0	N.A. (N.A., N.A.)	7	2 (28.6)	N.A. (0.72, N.A.)	N.M.E. 0.1161	
BASELINE LDH (IU/L)								0.6340
< 300	43	11 (25.6)	38.54 (23.49, N.A.)	40	4 (10.0)	N.A. (30.26, N.A.)	2.004 (0.632, 6.354) 0.2284	
>= 300	14	3 (21.4)	23.95 (23.95, N.A.)	15	3 (20.0)	N.A. (3.38, N.A.)	1.065 (0.210, 5.402) 0.9394	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE CREATININE CLEARANCE (ML/MIN)								0.6948
< 60	14	4 (28.6)	27.60 (4.53, N.A.)	16	2 (12.5)	13.34 (13.34, N.A.)	0.880 (0.115, 6.708) 0.9019	
>= 60	45	10 (22.2)	38.54 (23.49, N.A.)	39	5 (12.8)	N.A. (30.26, N.A.)	1.728 (0.588, 5.075) 0.3131	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NUMBER OF LINES OF PRIOR THERAPY (CRF)								0.7624
2-3	35	6 (17.1)	38.54 (24.87, N.A.)	35	3 (8.6)	N.A. (N.A., N.A.)	1.710 (0.424, 6.890) 0.4452	
>= 4	25	8 (32.0)	23.95 (5.19, N.A.)	20	4 (20.0)	30.26 (13.34, 30.26)	1.622 (0.419, 6.279) 0.4778	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 6 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.7276
NORTH AMERICA	3	1 (33.3)	N.M.E.	6	0	N.M.E.	N.M.E.	
EUROPE	44	8 (18.2)	38.54 (23.95, N.A.)	43	5 (11.6)	N.A. (30.26, N.A.)	1.435 (0.466, 4.413) 0.5264	
JAPAN	13	5 (38.5)	24.87 (5.19, N.A.)	6	2 (33.3)	N.A. (2.99, N.A.)	0.926 (0.166, 5.158) 0.9299	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS I								0.8647
0-1	56	13 (23.2)	38.54 (23.95, N.A.)	47	6 (12.8)	N.A. (30.26, N.A.)	1.617 (0.609, 4.292) 0.3297	
2	4	1 (25.0)	N.A. (4.53, N.A.)	8	1 (12.5)	N.A. (2.37, N.A.)	2.092 (0.129, 33.809) 0.5952	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 7 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS II								0.6934
0	28	9 (32.1)	38.54 (23.95, N.A.)	22	3 (13.6)	N.A. (N.A., N.A.)	1.916 (0.516, 7.122) 0.3221	
>= 1	32	5 (15.6)	27.60 (23.49, 27.60)	33	4 (12.1)	30.26 (13.34, N.A.)	1.610 (0.372, 6.969) 0.5207	
PRIOR STEM CELL TRANSPLANT								0.9925
YES	31	6 (19.4)	23.95 (23.49, N.A.)	32	7 (21.9)	30.26 (13.34, N.A.)	1.092 (0.348, 3.426) 0.8806	
NO	29	8 (27.6)	38.54 (24.87, N.A.)	23	0	N.A. (N.A., N.A.)	N.M.E. 0.0523	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 8 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
MYELOMA RISK CATEGORY								0.7018
HIGH RISK	6	2 (33.3)	N.A. (0.72, N.A.)	10	1 (10.0)	N.A. (0.72, N.A.)	3.151 (0.284, 35.008) 0.3200	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	12 (26.1)	27.60 (23.49, N.A.)	39	5 (12.8)	N.A. (30.26, N.A.)	2.028 (0.705, 5.836) 0.1812	
NOT EVALUABLE	6	0	N.A. (N.A., N.A.)	5	1 (20.0)	N.A. (2.37, N.A.)	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	2 (33.3)	N.M.E.	N.M.E.	
NO	47	13 (27.7)	N.M.E.	39	4 (10.3)	N.M.E.	N.M.E.	
NOT REPORTED	10	1 (10.0)	N.M.E.	10	1 (10.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:15

Protocol: CA204125

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	1 (14.3)	N.M.E.	2	0	N.M.E.	N.M.E.	
NO	44	12 (27.3)	N.M.E.	42	6 (14.3)	N.M.E.	N.M.E.	
NOT REPORTED	9	1 (11.1)	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								0.6763
YES	7	2 (28.6)	N.A. (0.72, N.A.)	9	1 (11.1)	N.A. (3.38, N.A.)	2.282 (0.204, 25.556) 0.4914	
NO	43	11 (25.6)	27.60 (23.95, N.A.)	35	5 (14.3)	30.26 (13.34, N.A.)	1.594 (0.549, 4.622) 0.3869	
NOT REPORTED	10	1 (10.0)	N.A. (23.49, N.A.)	11	1 (9.1)	N.A. (2.37, N.A.)	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:15

Protocol: CA204125 Page 10 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	7 (25.0)	N.M.E.	29	2 (6.9)	N.M.E.	N.M.E.	
NO	22	6 (27.3)	N.M.E.	13	3 (23.1)	N.M.E.	N.M.E.	
NOT REPORTED	10	1 (10.0)	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	13 (27.7)	N.M.E.	41	5 (12.2)	N.M.E.	N.M.E.	
NOT REPORTED	11	1 (9.1)	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy. Second Primary Malignancies are included beyond this period. If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:15

Protocol: CA204125 Page 1 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

	E-Pd			Pd			E-Pd vs. Pd	
On-study AESIs with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	2 (3.3)	N.A. (N.A., N.A.)	55	0	N.A. (N.A., N.A.)	N.M.E. 0.4283	
AGE I								N.M.E.
< 75	47	2 (4.3)	N.M.E.	43	0	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	0	N.M.E.	N.M.E.	
AGE II								N.M.E.
< 65	22	0	N.M.E.	21	0	N.M.E.	N.M.E.	
>= 65	38	2 (5.3)	N.M.E.	34	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 2 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

	E-Pd			Pd			E-Pd vs. Pd	
On-study AESIs with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	0	N.M.E.	21	0	N.M.E.	N.M.E.	
>= 65 AND < 75	25	2 (8.0)	N.M.E.	22	0	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	0	N.M.E.	N.M.E.	
RACE								N.M.E.
WHITE	45	0	N.M.E.	45	0	N.M.E.	N.M.E.	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	2 (13.3)	N.M.E.	8	0	N.M.E.	N.M.E.	
OTHER	0	0	N.M.E.	2	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 3 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

	E-Pd			Pd			E-Pd vs. Pd	
On-study AESIs with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
MALE	32	1 (3.1)	N.M.E.	34	0	N.M.E.	N.M.E.	
FEMALE	28	1 (3.6)	N.M.E.	21	0	N.M.E.	N.M.E.	
BASELINE B2 MICROGLOBULIN (MG/L)								N.M.E.
< 3.5	35	2 (5.7)	N.M.E.	31	0	N.M.E.	N.M.E.	
>= 3.5	24	0	N.M.E.	24	0	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 4 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

	E-Pd			Pd			E-Pd vs. Pd	
On-study AESIs with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ISS STAGE AT STUDY ENTRY (CRF)								N.M.E.
I-II	53	2 (3.8)	N.M.E.	48	0	N.M.E.	N.M.E.	
III	7	0	N.M.E.	7	0	N.M.E.	N.M.E.	
BASELINE LDH (IU/L)								N.M.E.
< 300	43	2 (4.7)	N.M.E.	40	0	N.M.E.	N.M.E.	
>= 300	14	0	N.M.E.	15	0	N.M.E.	N.M.E.	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 5 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE CREATININE CLEARANCE (ML/MIN)								N.M.E.
< 60	14	1 (7.1)	N.M.E.	16	0	N.M.E.	N.M.E.	
>= 60	45	1 (2.2)	N.M.E.	39	0	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NUMBER OF LINES OF PRIOR THERAPY (CRF)								N.M.E.
2-3	35	2 (5.7)	N.M.E.	35	0	N.M.E.	N.M.E.	
>= 4	25	0	N.M.E.	20	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 6 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
EUROPE	44	0	N.M.E.	43	0	N.M.E.	N.M.E.	
JAPAN	13	2 (15.4)	N.M.E.	6	0	N.M.E.	N.M.E.	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS I								N.M.E.
0-1	56	2 (3.6)	N.M.E.	47	0	N.M.E.	N.M.E.	
2	4	0	N.M.E.	8	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 7 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study AESIs with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS II								N.M.E.
0	28	2 (7.1)	N.M.E.	22	0	N.M.E.	N.M.E.	
>= 1	32	0	N.M.E.	33	0	N.M.E.	N.M.E.	
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	0	N.M.E.	32	0	N.M.E.	N.M.E.	
NO	29	2 (6.9)	N.M.E.	23	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 8 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

	E-Pd			Pd			E-Pd vs. Pd	
On-study AESIs with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
MYELOMA RISK CATEGORY								N.M.E.
HIGH RISK	6	0	N.M.E.	10	0	N.M.E.	N.M.E.	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	2 (4.3)	N.M.E.	39	0	N.M.E.	N.M.E.	
NOT EVALUABLE	6	0	N.M.E.	5	0	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
NO	47	2 (4.3)	N.M.E.	39	0	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 9 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

	E-Pd			Pd			E-Pd vs. Pd	
On-study AESIs with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	0	N.M.E.	2	0	N.M.E.	N.M.E.	
NO	44	2 (4.5)	N.M.E.	42	0	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	0	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								N.M.E.
YES	7	0	N.M.E.	9	0	N.M.E.	N.M.E.	
NO	43	2 (4.7)	N.M.E.	35	0	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	11	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 10 of 10

Subgroup Time-Adjusted Analyses of On-study Adverse Events of Special Interest with CTCAE Grade 3-4-5
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

	E-Pd			Pd			E-Pd vs. Pd	
On-study AESIs with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	0	N.M.E.	29	0	N.M.E.	N.M.E.	
NO	22	2 (9.1)	N.M.E.	13	0	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	0	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	2 (4.3)	N.M.E.	41	0	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 26APR2021:17:05:27

Protocol: CA204125 Page 1 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
OVERALL	60	1 (1.7)	N.A. (N.A., N.A.)	55	0	N.A. (N.A., N.A.)	N.M.E. 0.3749	
AGE I								N.M.E.
< 75	47	1 (2.1)	N.M.E.	43	0	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	0	N.M.E.	N.M.E.	
AGE II								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	0	N.M.E.	N.M.E.	
>= 65	38	0	N.M.E.	34	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 28MAY2021:09:24:57

Protocol: CA204125 Page 2 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	0	N.M.E.	N.M.E.	
>= 65 AND < 75	25	0	N.M.E.	22	0	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	0	N.M.E.	N.M.E.	
RACE								N.M.E.
WHITE	45	1 (2.2)	N.M.E.	45	0	N.M.E.	N.M.E.	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	0	N.M.E.	8	0	N.M.E.	N.M.E.	
OTHER	0	0	N.M.E.	2	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 28MAY2021:09:24:57

Protocol: CA204125 Page 3 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
SEX								N.M.E.
MALE	32	1 (3.1)	N.M.E.	34	0	N.M.E.	N.M.E.	
FEMALE	28	0	N.M.E.	21	0	N.M.E.	N.M.E.	
BASELINE B2 MICROGLOBULIN (MG/L)								N.M.E.
< 3.5	35	1 (2.9)	N.M.E.	31	0	N.M.E.	N.M.E.	
>= 3.5	24	0	N.M.E.	24	0	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 28MAY2021:09:24:57

Protocol: CA204125 Page 4 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
ISS STAGE AT STUDY ENTRY (CRF)								N.M.E.
I-II	53	1 (1.9)	N.M.E.	48	0	N.M.E.	N.M.E.	
III	7	0	N.M.E.	7	0	N.M.E.	N.M.E.	
BASELINE LDH (IU/L)								N.M.E.
< 300	43	1 (2.3)	N.M.E.	40	0	N.M.E.	N.M.E.	
>= 300	14	0	N.M.E.	15	0	N.M.E.	N.M.E.	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 28MAY2021:09:24:57

Protocol: CA204125 Page 5 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE CREATININE CLEARANCE (ML/MIN)								N.M.E.
< 60	14	0	N.M.E.	16	0	N.M.E.	N.M.E.	
>= 60	45	1 (2.2)	N.M.E.	39	0	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NUMBER OF LINES OF PRIOR THERAPY (CRF)								N.M.E.
2-3	35	0	N.M.E.	35	0	N.M.E.	N.M.E.	
>= 4	25	1 (4.0)	N.M.E.	20	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 28MAY2021:09:24:57

Protocol: CA204125 Page 6 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
EUROPE	44	1 (2.3)	N.M.E.	43	0	N.M.E.	N.M.E.	
JAPAN	13	0	N.M.E.	6	0	N.M.E.	N.M.E.	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS I								N.M.E.
0-1	56	1 (1.8)	N.M.E.	47	0	N.M.E.	N.M.E.	
2	4	0	N.M.E.	8	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 28MAY2021:09:24:57

Protocol: CA204125 Page 7 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS II								N.M.E.
0	28	1 (3.6)	N.M.E.	22	0	N.M.E.	N.M.E.	
>= 1	32	0	N.M.E.	33	0	N.M.E.	N.M.E.	
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	1 (3.2)	N.M.E.	32	0	N.M.E.	N.M.E.	
NO	29	0	N.M.E.	23	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
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Protocol: CA204125 Page 8 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
MYELOMA RISK CATEGORY								N.M.E.
HIGH RISK	6	0	N.M.E.	10	0	N.M.E.	N.M.E.	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	1 (2.2)	N.M.E.	39	0	N.M.E.	N.M.E.	
NOT EVALUABLE	6	0	N.M.E.	5	0	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
NO	47	1 (2.1)	N.M.E.	39	0	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 28MAY2021:09:24:57

Protocol: CA204125 Page 9 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	0	N.M.E.	2	0	N.M.E.	N.M.E.	
NO	44	1 (2.3)	N.M.E.	42	0	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	0	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								N.M.E.
YES	7	0	N.M.E.	9	0	N.M.E.	N.M.E.	
NO	43	1 (2.3)	N.M.E.	35	0	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	11	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 28MAY2021:09:24:57

Protocol: CA204125 Page 10 of 10

Subgroup Time-Adjusted Analyses of On-study Serious Adverse Events of Special Interest
on Hazard Ratio for any AEs of Special Interest
All Treated Subjects

PATIENTS WITH ANY AE OF SPECIAL INTEREST

On-study SAESIs Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	0	N.M.E.	29	0	N.M.E.	N.M.E.	
NO	22	1 (4.5)	N.M.E.	13	0	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	0	N.M.E.	N.M.E.	
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	1 (2.1)	N.M.E.	41	0	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd in one subgroup, display HR as n.m.e. (1) KME of median time
(2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Second Primary Malignancies not reported because CTCAE grade and seriousness not assessed for Second Primary Malignancies events.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaesi-ebr2453.sas 28MAY2021:09:24:57

Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
OVERALL	60	4 (6.7)	N.A. (N.A., N.A.)	55	8 (14.5)	N.A. (12.71, N.A.)	0.280 (0.082, 0.957) 0.0314	
AGE I								N.M.E.
< 75	47	2 (4.3)	N.M.E.	43	7 (16.3)	N.M.E.	N.M.E.	
>= 75	13	2 (15.4)	N.M.E.	12	1 (8.3)	N.M.E.	N.M.E.	
AGE II								0.9937
< 65	22	0	N.A. (N.A., N.A.)	21	2 (9.5)	N.A. (7.49, N.A.)	N.M.E. 0.0725	
>= 65	38	4 (10.5)	N.A. (17.18, N.A.)	34	6 (17.6)	N.A. (12.71, N.A.)	0.418 (0.116, 1.510) 0.1706	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	0	N.M.E.	21	2 (9.5)	N.M.E.	N.M.E.	
>= 65 AND < 75	25	2 (8.0)	N.M.E.	22	5 (22.7)	N.M.E.	N.M.E.	
>= 75	13	2 (15.4)	N.M.E.	12	1 (8.3)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
RACE								N.M.E.
WHITE	45	0	N.M.E.	45	5 (11.1)	N.M.E.	N.M.E.	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	4 (26.7)	N.M.E.	8	2 (25.0)	N.M.E.	N.M.E.	
OTHER	0	0	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	32	1 (3.1)	N.M.E.	34	3 (8.8)	N.M.E.	N.M.E.	
FEMALE	28	3 (10.7)	N.M.E.	21	5 (23.8)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 4 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE B2 MICROGLOBULIN (MG/L)								0.9941
< 3.5	35	4 (11.4)	N.A. (N.A., N.A.)	31	6 (19.4)	N.A. (12.71, N.A.)	0.414 (0.116, 1.487) 0.1636	
>= 3.5	24	0	N.A. (N.A., N.A.)	24	2 (8.3)	N.A. (7.49, N.A.)	N.M.E. 0.0896	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ISS STAGE AT STUDY ENTRY (CRF)								0.9928
I-II	53	4 (7.5)	N.A. (N.A., N.A.)	48	7 (14.6)	N.A. (14.75, N.A.)	0.331 (0.094, 1.164) 0.0718	
III	7	0	N.A. (N.A., N.A.)	7	1 (14.3)	N.A. (7.49, N.A.)	N.M.E. 0.2207	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE LDH								0.9927
< 300	43	4 (9.3)	N.A. (N.A., N.A.)	40	6 (15.0)	N.A. (12.71, N.A.)	0.360 (0.098, 1.315) 0.1084	
>= 300	14	0	N.A. (N.A., N.A.)	15	2 (13.3)	N.A. (7.49, N.A.)	N.M.E. 0.2084	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE CREATININE CLEARANCE (ML/MIN)								N.M.E.
< 60	14	2 (14.3)	N.M.E.	16	2 (12.5)	N.M.E.	N.M.E.	
>= 60	45	2 (4.4)	N.M.E.	39	6 (15.4)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 6 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
NUMBER OF LINES OF PRIOR THERAPY (CRF)								N.M.E.
2-3	35	1 (2.9)	N.M.E.	35	6 (17.1)	N.M.E.	N.M.E.	
>= 4	25	3 (12.0)	N.M.E.	20	2 (10.0)	N.M.E.	N.M.E.	
REGION								N.M.E.
NORTH AMERICA	3	0	N.M.E.	6	1 (16.7)	N.M.E.	N.M.E.	
EUROPE	44	0	N.M.E.	43	5 (11.6)	N.M.E.	N.M.E.	
JAPAN	13	4 (30.8)	N.M.E.	6	2 (33.3)	N.M.E.	N.M.E.	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 7 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events / Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS I								0.9929
0-1	56	4 (7.1)	N.A. (N.A., N.A.)	47	6 (12.8)	N.A. (14.75, N.A.)	0.346 (0.095, 1.260) 0.0935	
2	4	0	N.A. (N.A., N.A.)	8	2 (25.0)	7.49 (3.25, 7.49)	N.M.E. 0.5637	
BASELINE ECOG PERFORMANCE STATUS II								N.M.E.
0	28	3 (10.7)	N.M.E.	22	4 (18.2)	N.M.E.	N.M.E.	
>= 1	32	1 (3.1)	N.M.E.	33	4 (12.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 8 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	0	N.M.E.	32	5 (15.6)	N.M.E.	N.M.E.	
NO	29	4 (13.8)	N.M.E.	23	3 (13.0)	N.M.E.	N.M.E.	
MYELOMA RISK CATEGORY								N.M.E.
HIGH RISK	6	0	N.M.E.	10	0	N.M.E.	N.M.E.	
LOW RISK	2	0	N.M.E.	1	1 (100.0)	N.M.E.	N.M.E.	
STANDARD RISK	46	4 (8.7)	N.M.E.	39	5 (12.8)	N.M.E.	N.M.E.	
NOT EVALUABLE	6	0	N.M.E.	5	2 (40.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
NO	47	4 (8.5)	N.M.E.	39	4 (10.3)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	4 (40.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 10 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	1 (14.3)	N.M.E.	2	0	N.M.E.	N.M.E.	
NO	44	3 (6.8)	N.M.E.	42	4 (9.5)	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	4 (36.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								N.M.E.
YES	7	1 (14.3)	N.M.E.	9	0	N.M.E.	N.M.E.	
NO	43	3 (7.0)	N.M.E.	35	4 (11.4)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	11	4 (36.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 12 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	2 (7.1)	N.M.E.	29	2 (6.9)	N.M.E.	N.M.E.	
NO	22	2 (9.1)	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	4 (30.8)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	4 (8.5)	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	4 (30.8)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 14 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	3 (5.0)	N.A. (N.A., N.A.)	55	13 (23.6)	40.25 (40.25, N.A.)	0.164 (0.046, 0.583) 0.0016	
AGE I								0.9928
< 75	47	3 (6.4)	N.A. (N.A., N.A.)	43	11 (25.6)	40.25 (9.69, N.A.)	0.189 (0.052, 0.688) 0.0050	
>= 75	13	0	N.A. (N.A., N.A.)	12	2 (16.7)	N.A. (1.41, N.A.)	N.M.E. 0.1324	
AGE II								N.M.E.
< 65	22	2 (9.1)	N.M.E.	21	6 (28.6)	N.M.E.	N.M.E.	
>= 65	38	1 (2.6)	N.M.E.	34	7 (20.6)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 15 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	2 (9.1)	N.M.E.	21	6 (28.6)	N.M.E.	N.M.E.	
>= 65 AND < 75	25	1 (4.0)	N.M.E.	22	5 (22.7)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 16 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
RACE								0.5902
WHITE	45	2 (4.4)	N.A. (N.A., N.A.)	45	10 (22.2)	N.A. (40.25, N.A.)	0.171 (0.037, 0.787) 0.0106	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	1 (6.7)	N.A. (15.38, N.A.)	8	1 (12.5)	N.A. (1.58, N.A.)	0.276 (0.015, 5.136) 0.3633	
OTHER	0	0	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	32	1 (3.1)	N.M.E.	34	6 (17.6)	N.M.E.	N.M.E.	
FEMALE	28	2 (7.1)	N.M.E.	21	7 (33.3)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 17 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE B2 MICROGLOBULIN (MG/L)								0.9853
< 3.5	35	1 (2.9)	N.A. (N.A., N.A.)	31	5 (16.1)	N.A. (40.25, N.A.)	0.157 (0.018, 1.369) 0.0563	
>= 3.5	24	2 (8.3)	N.A. (14.00, N.A.)	24	8 (33.3)	N.A. (3.25, N.A.)	0.103 (0.013, 0.827) 0.0088	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ISS STAGE AT STUDY ENTRY (CRF)								0.9926
I-II	53	3 (5.7)	N.A. (N.A., N.A.)	48	9 (18.8)	N.A. (40.25, N.A.)	0.242 (0.064, 0.912) 0.0239	
III	7	0	N.A. (N.A., N.A.)	7	4 (57.1)	6.98 (1.41, N.A.)	N.M.E. 0.0352	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 18 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE LDH								N.M.E.
< 300	43	0	N.M.E.	40	8 (20.0)	N.M.E.	N.M.E.	
>= 300	14	3 (21.4)	N.M.E.	15	5 (33.3)	N.M.E.	N.M.E.	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE CREATININE CLEARANCE (ML/MIN)								0.9923
< 60	14	0	N.A. (N.A., N.A.)	16	4 (25.0)	N.A. (2.46, N.A.)	N.M.E. 0.0603	
>= 60	45	3 (6.7)	N.A. (N.A., N.A.)	39	9 (23.1)	40.25 (40.25, N.A.)	0.231 (0.062, 0.865) 0.0183	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 19 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF LINES OF PRIOR THERAPY (CRF)								0.6229
2-3	35	2 (5.7)	N.A. (N.A., N.A.)	35	8 (22.9)	40.25 (40.25, N.A.)	0.210 (0.044, 0.998) 0.0309	
>= 4	25	1 (4.0)	N.A. (14.00, N.A.)	20	5 (25.0)	N.A. (4.27, N.A.)	0.107 (0.012, 0.964) 0.0181	
REGION								0.5628
NORTH AMERICA	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
EUROPE	44	2 (4.5)	N.A. (N.A., N.A.)	43	12 (27.9)	40.25 (9.69, N.A.)	0.132 (0.029, 0.596) 0.0021	
JAPAN	13	1 (7.7)	N.A. (15.38, N.A.)	6	1 (16.7)	N.A. (1.58, N.A.)	0.257 (0.014, 4.629) 0.3270	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 20 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS I								0.9923
0-1	56	3 (5.4)	N.A. (N.A., N.A.)	47	11 (23.4)	N.A. (40.25, N.A.)	0.186 (0.051, 0.676) 0.0045	
2	4	0	N.A. (N.A., N.A.)	8	2 (25.0)	9.69 (1.18, 9.69)	N.M.E. 0.4497	
BASELINE ECOG PERFORMANCE STATUS II								0.8874
0	28	1 (3.6)	N.A. (N.A., N.A.)	22	4 (18.2)	N.A. (N.A., N.A.)	0.154 (0.017, 1.392) 0.0561	
>= 1	32	2 (6.3)	N.A. (15.38, N.A.)	33	9 (27.3)	40.25 (9.69, 40.25)	0.180 (0.035, 0.912) 0.0223	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 21 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	2 (6.5)	N.M.E.	32	6 (18.8)	N.M.E.	N.M.E.	
NO	29	1 (3.4)	N.M.E.	23	7 (30.4)	N.M.E.	N.M.E.	
MYELOMA RISK CATEGORY								0.9946
HIGH RISK	6	0	N.A. (N.A., N.A.)	10	4 (40.0)	N.A. (1.18, N.A.)	N.M.E. 0.0937	
LOW RISK	2	1 (50.0)	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	2 (4.3)	N.A. (N.A., N.A.)	39	8 (20.5)	N.A. (40.25, N.A.)	0.198 (0.041, 0.950) 0.0254	
NOT EVALUABLE	6	0	N.A. (N.A., N.A.)	5	1 (20.0)	9.69 (N.A., N.A.)	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 22 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	4 (66.7)	N.M.E.	N.M.E.	
NO	47	3 (6.4)	N.M.E.	39	8 (20.5)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	1 (10.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 23 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	1 (14.3)	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
NO	44	2 (4.5)	N.M.E.	42	11 (26.2)	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 24 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								0.9940
YES	7	0	N.A. (N.A., N.A.)	9	3 (33.3)	N.A. (1.41, N.A.)	N.M.E. 0.0793	
NO	43	3 (7.0)	N.A. (N.A., N.A.)	35	9 (25.7)	40.25 (N.A., N.A.)	0.223 (0.059, 0.839) 0.0157	
NOT REPORTED	10	0	N.A. (N.A., N.A.)	11	1 (9.1)	N.A. (9.69, N.A.)	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 25 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	1 (3.6)	N.M.E.	29	8 (27.6)	N.M.E.	N.M.E.	
NO	22	2 (9.1)	N.M.E.	13	3 (23.1)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 26 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	3 (6.4)	N.M.E.	41	11 (26.8)	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 27 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	1 (1.7)	N.A. (N.A., N.A.)	55	7 (12.7)	N.A. (N.A., N.A.)	0.113 (0.014, 0.925) 0.0142	
AGE I								N.M.E.
< 75	47	1 (2.1)	N.M.E.	43	5 (11.6)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	
AGE II								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	
>= 65	38	0	N.M.E.	34	4 (11.8)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	25	0	N.M.E.	22	2 (9.1)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 29 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
RACE								N.M.E.
WHITE	45	1 (2.2)	N.M.E.	45	6 (13.3)	N.M.E.	N.M.E.	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	0	N.M.E.	8	0	N.M.E.	N.M.E.	
OTHER	0	0	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	32	0	N.M.E.	34	4 (11.8)	N.M.E.	N.M.E.	
FEMALE	28	1 (3.6)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 30 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE B2 MICROGLOBULIN (MG/L)								N.M.E.
< 3.5	35	0	N.M.E.	31	2 (6.5)	N.M.E.	N.M.E.	
>= 3.5	24	1 (4.2)	N.M.E.	24	5 (20.8)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ISS STAGE AT STUDY ENTRY (CRF)								N.M.E.
I-II	53	1 (1.9)	N.M.E.	48	3 (6.3)	N.M.E.	N.M.E.	
III	7	0	N.M.E.	7	4 (57.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 31 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE LDH								N.M.E.
< 300	43	0	N.M.E.	40	6 (15.0)	N.M.E.	N.M.E.	
>= 300	14	1 (7.1)	N.M.E.	15	1 (6.7)	N.M.E.	N.M.E.	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE CREATININE CLEARANCE (ML/MIN)								N.M.E.
< 60	14	0	N.M.E.	16	2 (12.5)	N.M.E.	N.M.E.	
>= 60	45	1 (2.2)	N.M.E.	39	5 (12.8)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 32 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF LINES OF PRIOR THERAPY (CRF)								N.M.E.
2-3	35	1 (2.9)	N.M.E.	35	5 (14.3)	N.M.E.	N.M.E.	
>= 4	25	0	N.M.E.	20	2 (10.0)	N.M.E.	N.M.E.	
REGION								N.M.E.
NORTH AMERICA	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
EUROPE	44	1 (2.3)	N.M.E.	43	7 (16.3)	N.M.E.	N.M.E.	
JAPAN	13	0	N.M.E.	6	0	N.M.E.	N.M.E.	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 33 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS I								N.M.E.
0-1	56	1 (1.8)	N.M.E.	47	6 (12.8)	N.M.E.	N.M.E.	
2	4	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS II								N.M.E.
0	28	0	N.M.E.	22	3 (13.6)	N.M.E.	N.M.E.	
>= 1	32	1 (3.1)	N.M.E.	33	4 (12.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 34 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	0	N.M.E.	32	3 (9.4)	N.M.E.	N.M.E.	
NO	29	1 (3.4)	N.M.E.	23	4 (17.4)	N.M.E.	N.M.E.	
MYELOMA RISK CATEGORY								N.M.E.
HIGH RISK	6	0	N.M.E.	10	3 (30.0)	N.M.E.	N.M.E.	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	1 (2.2)	N.M.E.	39	3 (7.7)	N.M.E.	N.M.E.	
NOT EVALUABLE	6	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	2 (33.3)	N.M.E.	N.M.E.	
NO	47	1 (2.1)	N.M.E.	39	4 (10.3)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	1 (10.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 36 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	1 (14.3)	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
NO	44	0	N.M.E.	42	5 (11.9)	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 37 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								N.M.E.
YES	7	0	N.M.E.	9	2 (22.2)	N.M.E.	N.M.E.	
NO	43	1 (2.3)	N.M.E.	35	4 (11.4)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 38 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	1 (3.6)	N.M.E.	29	5 (17.2)	N.M.E.	N.M.E.	
NO	22	0	N.M.E.	13	0	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	1 (2.1)	N.M.E.	41	5 (12.2)	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 40 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
OVERALL	60	3 (5.0)	N.A. (26.25, N.A.)	55	6 (10.9)	N.A. (34.07, N.A.)	0.332 (0.081, 1.356) 0.1079	
AGE I								N.M.E.
< 75	47	3 (6.4)	N.M.E.	43	5 (11.6)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	1 (8.3)	N.M.E.	N.M.E.	
AGE II								N.M.E.
< 65	22	0	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	
>= 65	38	3 (7.9)	N.M.E.	34	3 (8.8)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 41 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	0	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	25	3 (12.0)	N.M.E.	22	2 (9.1)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	1 (8.3)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 42 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
RACE								N.M.E.
WHITE	45	1 (2.2)	N.M.E.	45	3 (6.7)	N.M.E.	N.M.E.	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	2 (13.3)	N.M.E.	8	2 (25.0)	N.M.E.	N.M.E.	
OTHER	0	0	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	32	2 (6.3)	N.M.E.	34	3 (8.8)	N.M.E.	N.M.E.	
FEMALE	28	1 (3.6)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 43 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE B2 MICROGLOBULIN (MG/L)								N.M.E.
< 3.5	35	2 (5.7)	N.M.E.	31	5 (16.1)	N.M.E.	N.M.E.	
>= 3.5	24	1 (4.2)	N.M.E.	24	1 (4.2)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ISS STAGE AT STUDY ENTRY (CRF)								N.M.E.
I-II	53	2 (3.8)	N.M.E.	48	6 (12.5)	N.M.E.	N.M.E.	
III	7	1 (14.3)	N.M.E.	7	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 44 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE LDH								N.M.E.
< 300	43	3 (7.0)	N.M.E.	40	4 (10.0)	N.M.E.	N.M.E.	
>= 300	14	0	N.M.E.	15	2 (13.3)	N.M.E.	N.M.E.	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE CREATININE CLEARANCE (ML/MIN)								N.M.E.
< 60	14	1 (7.1)	N.M.E.	16	3 (18.8)	N.M.E.	N.M.E.	
>= 60	45	2 (4.4)	N.M.E.	39	3 (7.7)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 45 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
NUMBER OF LINES OF PRIOR THERAPY (CRF)								N.M.E.
2-3	35	2 (5.7)	N.M.E.	35	3 (8.6)	N.M.E.	N.M.E.	
>= 4	25	1 (4.0)	N.M.E.	20	3 (15.0)	N.M.E.	N.M.E.	
REGION								N.M.E.
NORTH AMERICA	3	0	N.M.E.	6	1 (16.7)	N.M.E.	N.M.E.	
EUROPE	44	1 (2.3)	N.M.E.	43	4 (9.3)	N.M.E.	N.M.E.	
JAPAN	13	2 (15.4)	N.M.E.	6	1 (16.7)	N.M.E.	N.M.E.	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 46 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS I								N.M.E.
0-1	56	3 (5.4)	N.M.E.	47	6 (12.8)	N.M.E.	N.M.E.	
2	4	0	N.M.E.	8	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS II								N.M.E.
0	28	2 (7.1)	N.M.E.	22	3 (13.6)	N.M.E.	N.M.E.	
>= 1	32	1 (3.1)	N.M.E.	33	3 (9.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 47 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	0	N.M.E.	32	5 (15.6)	N.M.E.	N.M.E.	
NO	29	3 (10.3)	N.M.E.	23	1 (4.3)	N.M.E.	N.M.E.	
MYELOMA RISK CATEGORY								N.M.E.
HIGH RISK	6	0	N.M.E.	10	0	N.M.E.	N.M.E.	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	3 (6.5)	N.M.E.	39	6 (15.4)	N.M.E.	N.M.E.	
NOT EVALUABLE	6	0	N.M.E.	5	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 48 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events / Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	1 (16.7)	N.M.E.	N.M.E.	
NO	47	3 (6.4)	N.M.E.	39	3 (7.7)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	2 (20.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 49 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	2 (28.6)	N.M.E.	2	0	N.M.E.	N.M.E.	
NO	44	1 (2.3)	N.M.E.	42	4 (9.5)	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	2 (18.2)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 50 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								N.M.E.
YES	7	0	N.M.E.	9	1 (11.1)	N.M.E.	N.M.E.	
NO	43	3 (7.0)	N.M.E.	35	3 (8.6)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	11	2 (18.2)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 51 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	2 (7.1)	N.M.E.	29	1 (3.4)	N.M.E.	N.M.E.	
NO	22	1 (4.5)	N.M.E.	13	3 (23.1)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 52 of 52

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Reproductive System and Breast Disorders

Adverse Events / Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	3 (6.4)	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:21

Protocol: CA204125 Page 1 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	2 (3.3)	N.A. (N.A., N.A.)	55	11 (20.0)	N.A. (40.25, N.A.)	0.139 (0.031, 0.635) 0.0031	
AGE I								0.9937
< 75	47	2 (4.3)	N.A. (N.A., N.A.)	43	9 (20.9)	N.A. (40.25, N.A.)	0.167 (0.036, 0.780) 0.0101	
>= 75	13	0	N.A. (N.A., N.A.)	12	2 (16.7)	N.A. (1.41, N.A.)	N.M.E. 0.1324	
AGE II								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	4 (19.0)	N.M.E.	N.M.E.	
>= 65	38	1 (2.6)	N.M.E.	34	7 (20.6)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 2 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	4 (19.0)	N.M.E.	N.M.E.	
>= 65 AND < 75	25	1 (4.0)	N.M.E.	22	5 (22.7)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 3 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9998
WHITE	45	2 (4.4)	N.A. (N.A., N.A.)	45	9 (20.0)	N.A. (40.25, N.A.)	0.190 (0.040, 0.889) 0.0190	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	0	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
OTHER	0	0	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	32	1 (3.1)	N.M.E.	34	6 (17.6)	N.M.E.	N.M.E.	
FEMALE	28	1 (3.6)	N.M.E.	21	5 (23.8)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 4 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE B2 MICROGLOBULIN (MG/L)								N.M.E.
< 3.5	35	0	N.M.E.	31	4 (12.9)	N.M.E.	N.M.E.	
>= 3.5	24	2 (8.3)	N.M.E.	24	7 (29.2)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ISS STAGE AT STUDY ENTRY (CRF)								N.M.E.
I-II	53	2 (3.8)	N.M.E.	48	7 (14.6)	N.M.E.	N.M.E.	
III	7	0	N.M.E.	7	4 (57.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 5 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE LDH								N.M.E.
< 300	43	0	N.M.E.	40	6 (15.0)	N.M.E.	N.M.E.	
>= 300	14	2 (14.3)	N.M.E.	15	5 (33.3)	N.M.E.	N.M.E.	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE CREATININE CLEARANCE (ML/MIN)								0.9934
< 60	14	0	N.A. (N.A., N.A.)	16	3 (18.8)	N.A. (N.A., N.A.)	N.M.E. 0.1113	
>= 60	45	2 (4.4)	N.A. (N.A., N.A.)	39	8 (20.5)	N.A. (40.25, N.A.)	0.180 (0.038, 0.862) 0.0164	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 6 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF LINES OF PRIOR THERAPY (CRF)								N.M.E.
2-3	35	1 (2.9)	N.M.E.	35	8 (22.9)	N.M.E.	N.M.E.	
>= 4	25	1 (4.0)	N.M.E.	20	3 (15.0)	N.M.E.	N.M.E.	
REGION								0.9995
NORTH AMERICA	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
EUROPE	44	2 (4.5)	N.A. (N.A., N.A.)	43	11 (25.6)	40.25 (9.69, N.A.)	0.144 (0.032, 0.657) 0.0039	
JAPAN	13	0	N.A. (N.A., N.A.)	6	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 7 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS I								0.9934
0-1	56	2 (3.6)	N.A. (N.A., N.A.)	47	9 (19.1)	N.A. (40.25, N.A.)	0.165 (0.035, 0.773) 0.0096	
2	4	0	N.A. (N.A., N.A.)	8	2 (25.0)	9.69 (1.18, 9.69)	N.M.E. 0.4497	
BASELINE ECOG PERFORMANCE STATUS II								N.M.E.
0	28	1 (3.6)	N.M.E.	22	4 (18.2)	N.M.E.	N.M.E.	
>= 1	32	1 (3.1)	N.M.E.	33	7 (21.2)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 8 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	1 (3.2)	N.M.E.	32	5 (15.6)	N.M.E.	N.M.E.	
NO	29	1 (3.4)	N.M.E.	23	6 (26.1)	N.M.E.	N.M.E.	
MYELOMA RISK CATEGORY								N.M.E.
HIGH RISK	6	0	N.M.E.	10	4 (40.0)	N.M.E.	N.M.E.	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	2 (4.3)	N.M.E.	39	6 (15.4)	N.M.E.	N.M.E.	
NOT EVALUABLE	6	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 9 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	3 (50.0)	N.M.E.	N.M.E.	
NO	47	2 (4.3)	N.M.E.	39	7 (17.9)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	1 (10.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 10 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	1 (14.3)	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
NO	44	1 (2.3)	N.M.E.	42	9 (21.4)	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 11 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								N.M.E.
YES	7	0	N.M.E.	9	3 (33.3)	N.M.E.	N.M.E.	
NO	43	2 (4.7)	N.M.E.	35	7 (20.0)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 12 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	1 (3.6)	N.M.E.	29	6 (20.7)	N.M.E.	N.M.E.	
NO	22	1 (4.5)	N.M.E.	13	3 (23.1)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	2 (4.3)	N.M.E.	41	9 (22.0)	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 14 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	1 (1.7)	N.A. (N.A., N.A.)	55	7 (12.7)	N.A. (N.A., N.A.)	0.113 (0.014, 0.925) 0.0142	
AGE I								N.M.E.
< 75	47	1 (2.1)	N.M.E.	43	5 (11.6)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	
AGE II								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	
>= 65	38	0	N.M.E.	34	4 (11.8)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 15 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	25	0	N.M.E.	22	2 (9.1)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								N.M.E.
WHITE	45	1 (2.2)	N.M.E.	45	6 (13.3)	N.M.E.	N.M.E.	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	0	N.M.E.	8	0	N.M.E.	N.M.E.	
OTHER	0	0	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	32	0	N.M.E.	34	4 (11.8)	N.M.E.	N.M.E.	
FEMALE	28	1 (3.6)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 17 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE B2 MICROGLOBULIN (MG/L)								N.M.E.
< 3.5	35	0	N.M.E.	31	2 (6.5)	N.M.E.	N.M.E.	
>= 3.5	24	1 (4.2)	N.M.E.	24	5 (20.8)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ISS STAGE AT STUDY ENTRY (CRF)								N.M.E.
I-II	53	1 (1.9)	N.M.E.	48	3 (6.3)	N.M.E.	N.M.E.	
III	7	0	N.M.E.	7	4 (57.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 18 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE LDH								N.M.E.
< 300	43	0	N.M.E.	40	6 (15.0)	N.M.E.	N.M.E.	
>= 300	14	1 (7.1)	N.M.E.	15	1 (6.7)	N.M.E.	N.M.E.	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE CREATININE CLEARANCE (ML/MIN)								N.M.E.
< 60	14	0	N.M.E.	16	2 (12.5)	N.M.E.	N.M.E.	
>= 60	45	1 (2.2)	N.M.E.	39	5 (12.8)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 19 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF LINES OF PRIOR THERAPY (CRF)								N.M.E.
2-3	35	1 (2.9)	N.M.E.	35	5 (14.3)	N.M.E.	N.M.E.	
>= 4	25	0	N.M.E.	20	2 (10.0)	N.M.E.	N.M.E.	
REGION								N.M.E.
NORTH AMERICA	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
EUROPE	44	1 (2.3)	N.M.E.	43	7 (16.3)	N.M.E.	N.M.E.	
JAPAN	13	0	N.M.E.	6	0	N.M.E.	N.M.E.	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 20 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS I								N.M.E.
0-1	56	1 (1.8)	N.M.E.	47	6 (12.8)	N.M.E.	N.M.E.	
2	4	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS II								N.M.E.
0	28	0	N.M.E.	22	3 (13.6)	N.M.E.	N.M.E.	
>= 1	32	1 (3.1)	N.M.E.	33	4 (12.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 21 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	0	N.M.E.	32	3 (9.4)	N.M.E.	N.M.E.	
NO	29	1 (3.4)	N.M.E.	23	4 (17.4)	N.M.E.	N.M.E.	
MYELOMA RISK CATEGORY								N.M.E.
HIGH RISK	6	0	N.M.E.	10	3 (30.0)	N.M.E.	N.M.E.	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	1 (2.2)	N.M.E.	39	3 (7.7)	N.M.E.	N.M.E.	
NOT EVALUABLE	6	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 22 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	2 (33.3)	N.M.E.	N.M.E.	
NO	47	1 (2.1)	N.M.E.	39	4 (10.3)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	1 (10.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 23 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	1 (14.3)	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
NO	44	0	N.M.E.	42	5 (11.9)	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 24 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								N.M.E.
YES	7	0	N.M.E.	9	2 (22.2)	N.M.E.	N.M.E.	
NO	43	1 (2.3)	N.M.E.	35	4 (11.4)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 25 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	1 (3.6)	N.M.E.	29	5 (17.2)	N.M.E.	N.M.E.	
NO	22	0	N.M.E.	13	0	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 26 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-Study Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Adverse Events with CTCAE Grade 3-4-5 Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	1 (2.1)	N.M.E.	41	5 (12.2)	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:39

Protocol: CA204125 Page 1 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	2 (3.3)	N.A. (N.A., N.A.)	55	12 (21.8)	40.25 (40.25, N.A.)	0.124 (0.027, 0.563) 0.0014	
AGE I								0.9936
< 75	47	2 (4.3)	N.A. (N.A., N.A.)	43	10 (23.3)	40.25 (40.25, N.A.)	0.145 (0.031, 0.671) 0.0045	
>= 75	13	0	N.A. (N.A., N.A.)	12	2 (16.7)	N.A. (1.41, N.A.)	N.M.E. 0.1324	
AGE II								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	5 (23.8)	N.M.E.	N.M.E.	
>= 65	38	1 (2.6)	N.M.E.	34	7 (20.6)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 2 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	5 (23.8)	N.M.E.	N.M.E.	
>= 65 AND < 75	25	1 (4.0)	N.M.E.	22	5 (22.7)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 3 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9933
WHITE	45	2 (4.4)	N.A. (N.A., N.A.)	45	9 (20.0)	N.A. (40.25, N.A.)	0.190 (0.040, 0.889) 0.0190	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	0	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (1.58, N.A.)	N.M.E. 0.1709	
OTHER	0	0	N.M.E.	2	2 (100.0)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	32	1 (3.1)	N.M.E.	34	6 (17.6)	N.M.E.	N.M.E.	
FEMALE	28	1 (3.6)	N.M.E.	21	6 (28.6)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 4 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE B2 MICROGLOBULIN (MG/L)								N.M.E.
< 3.5	35	0	N.M.E.	31	5 (16.1)	N.M.E.	N.M.E.	
>= 3.5	24	2 (8.3)	N.M.E.	24	7 (29.2)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ISS STAGE AT STUDY ENTRY (CRF)								0.9934
I-II	53	2 (3.8)	N.A. (N.A., N.A.)	48	8 (16.7)	N.A. (40.25, N.A.)	0.193 (0.040, 0.927) 0.0229	
III	7	0	N.A. (N.A., N.A.)	7	4 (57.1)	6.98 (1.41, N.A.)	N.M.E. 0.0352	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 5 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE LDH								N.M.E.
< 300	43	0	N.M.E.	40	7 (17.5)	N.M.E.	N.M.E.	
>= 300	14	2 (14.3)	N.M.E.	15	5 (33.3)	N.M.E.	N.M.E.	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE CREATININE CLEARANCE (ML/MIN)								0.9934
< 60	14	0	N.A. (N.A., N.A.)	16	4 (25.0)	N.A. (2.46, N.A.)	N.M.E. 0.0603	
>= 60	45	2 (4.4)	N.A. (N.A., N.A.)	39	8 (20.5)	N.A. (40.25, N.A.)	0.180 (0.038, 0.862) 0.0164	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 6 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF LINES OF PRIOR THERAPY (CRF)								N.M.E.
2-3	35	1 (2.9)	N.M.E.	35	8 (22.9)	N.M.E.	N.M.E.	
>= 4	25	1 (4.0)	N.M.E.	20	4 (20.0)	N.M.E.	N.M.E.	
REGION								0.9931
NORTH AMERICA	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
EUROPE	44	2 (4.5)	N.A. (N.A., N.A.)	43	11 (25.6)	40.25 (9.69, N.A.)	0.144 (0.032, 0.657) 0.0039	
JAPAN	13	0	N.A. (N.A., N.A.)	6	1 (16.7)	N.A. (1.58, N.A.)	N.M.E. 0.1410	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 7 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS I								0.9929
0-1	56	2 (3.6)	N.A. (N.A., N.A.)	47	10 (21.3)	N.A. (40.25, N.A.)	0.145 (0.031, 0.669) 0.0044	
2	4	0	N.A. (N.A., N.A.)	8	2 (25.0)	9.69 (1.18, 9.69)	N.M.E. 0.4497	
BASELINE ECOG PERFORMANCE STATUS II								N.M.E.
0	28	1 (3.6)	N.M.E.	22	4 (18.2)	N.M.E.	N.M.E.	
>= 1	32	1 (3.1)	N.M.E.	33	8 (24.2)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 8 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	1 (3.2)	N.M.E.	32	6 (18.8)	N.M.E.	N.M.E.	
NO	29	1 (3.4)	N.M.E.	23	6 (26.1)	N.M.E.	N.M.E.	
MYELOMA RISK CATEGORY								N.M.E.
HIGH RISK	6	0	N.M.E.	10	4 (40.0)	N.M.E.	N.M.E.	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	2 (4.3)	N.M.E.	39	7 (17.9)	N.M.E.	N.M.E.	
NOT EVALUABLE	6	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 9 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	4 (66.7)	N.M.E.	N.M.E.	
NO	47	2 (4.3)	N.M.E.	39	7 (17.9)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	1 (10.0)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 10 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	1 (14.3)	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
NO	44	1 (2.3)	N.M.E.	42	10 (23.8)	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 11 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								0.9947
YES	7	0	N.A. (N.A., N.A.)	9	3 (33.3)	N.A. (1.41, N.A.)	N.M.E. 0.0793	
NO	43	2 (4.7)	N.A. (N.A., N.A.)	35	8 (22.9)	40.25 (N.A., N.A.)	0.178 (0.037, 0.849) 0.0152	
NOT REPORTED	10	0	N.A. (N.A., N.A.)	11	1 (9.1)	N.A. (9.69, N.A.)	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 12 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	1 (3.6)	N.M.E.	29	7 (24.1)	N.M.E.	N.M.E.	
NO	22	1 (4.5)	N.M.E.	13	3 (23.1)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 13 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	2 (4.3)	N.M.E.	41	10 (24.4)	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 14 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	60	1 (1.7)	N.A. (N.A., N.A.)	55	7 (12.7)	N.A. (N.A., N.A.)	0.113 (0.014, 0.925) 0.0142	
AGE I								N.M.E.
< 75	47	1 (2.1)	N.M.E.	43	5 (11.6)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	
AGE II								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	
>= 65	38	0	N.M.E.	34	4 (11.8)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 15 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE III								N.M.E.
< 65	22	1 (4.5)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	25	0	N.M.E.	22	2 (9.1)	N.M.E.	N.M.E.	
>= 75	13	0	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 16 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								N.M.E.
WHITE	45	1 (2.2)	N.M.E.	45	6 (13.3)	N.M.E.	N.M.E.	
BLACK OR AFRICAN AMERICAN	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ASIAN	15	0	N.M.E.	8	0	N.M.E.	N.M.E.	
OTHER	0	0	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	32	0	N.M.E.	34	4 (11.8)	N.M.E.	N.M.E.	
FEMALE	28	1 (3.6)	N.M.E.	21	3 (14.3)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 17 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE B2 MICROGLOBULIN (MG/L)								N.M.E.
< 3.5	35	0	N.M.E.	31	2 (6.5)	N.M.E.	N.M.E.	
>= 3.5	24	1 (4.2)	N.M.E.	24	5 (20.8)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
ISS STAGE AT STUDY ENTRY (CRF)								N.M.E.
I-II	53	1 (1.9)	N.M.E.	48	3 (6.3)	N.M.E.	N.M.E.	
III	7	0	N.M.E.	7	4 (57.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2453.sas 26APR2021:10:38:49

Protocol: CA204125 Page 18 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE LDH								N.M.E.
< 300	43	0	N.M.E.	40	6 (15.0)	N.M.E.	N.M.E.	
>= 300	14	1 (7.1)	N.M.E.	15	1 (6.7)	N.M.E.	N.M.E.	
NOT REPORTED	3	0	N.M.E.	0	0	N.M.E.	N.M.E.	
BASELINE CREATININE CLEARANCE (ML/MIN)								N.M.E.
< 60	14	0	N.M.E.	16	2 (12.5)	N.M.E.	N.M.E.	
>= 60	45	1 (2.2)	N.M.E.	39	5 (12.8)	N.M.E.	N.M.E.	
NOT REPORTED	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 19 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF LINES OF PRIOR THERAPY (CRF)								N.M.E.
2-3	35	1 (2.9)	N.M.E.	35	5 (14.3)	N.M.E.	N.M.E.	
>= 4	25	0	N.M.E.	20	2 (10.0)	N.M.E.	N.M.E.	
REGION								N.M.E.
NORTH AMERICA	3	0	N.M.E.	6	0	N.M.E.	N.M.E.	
EUROPE	44	1 (2.3)	N.M.E.	43	7 (16.3)	N.M.E.	N.M.E.	
JAPAN	13	0	N.M.E.	6	0	N.M.E.	N.M.E.	
REST OF THE WORLD	0	0	N.M.E.	0	0	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 20 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	E-Pd vs. Pd Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS I								N.M.E.
0-1	56	1 (1.8)	N.M.E.	47	6 (12.8)	N.M.E.	N.M.E.	
2	4	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS II								N.M.E.
0	28	0	N.M.E.	22	3 (13.6)	N.M.E.	N.M.E.	
>= 1	32	1 (3.1)	N.M.E.	33	4 (12.1)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 21 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

	E-Pd			Pd			E-Pd vs. Pd	
Serious Adverse Events Subgroups	N	Patients with Event n (%)	KME [95%CI](mon) (1)	N	Patients with Event n (%)	KME [95%CI](mon) (1)	HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR STEM CELL TRANSPLANT								N.M.E.
YES	31	0	N.M.E.	32	3 (9.4)	N.M.E.	N.M.E.	
NO	29	1 (3.4)	N.M.E.	23	4 (17.4)	N.M.E.	N.M.E.	
MYELOMA RISK CATEGORY								N.M.E.
HIGH RISK	6	0	N.M.E.	10	3 (30.0)	N.M.E.	N.M.E.	
LOW RISK	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
STANDARD RISK	46	1 (2.2)	N.M.E.	39	3 (7.7)	N.M.E.	N.M.E.	
NOT EVALUABLE	6	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	

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Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Protocol: CA204125 Page 22 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL 17P)								N.M.E.
YES	3	0	N.M.E.	6	2 (33.3)	N.M.E.	N.M.E.	
NO	47	1 (2.1)	N.M.E.	39	4 (10.3)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	10	1 (10.0)	N.M.E.	N.M.E.	

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Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
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Protocol: CA204125 Page 23 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(14; 16))								N.M.E.
YES	7	1 (14.3)	N.M.E.	2	1 (50.0)	N.M.E.	N.M.E.	
NO	44	0	N.M.E.	42	5 (11.9)	N.M.E.	N.M.E.	
NOT REPORTED	9	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

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Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
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Protocol: CA204125 Page 24 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
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by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (T(4; 14))								N.M.E.
YES	7	0	N.M.E.	9	2 (22.2)	N.M.E.	N.M.E.	
NO	43	1 (2.3)	N.M.E.	35	4 (11.4)	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	11	1 (9.1)	N.M.E.	N.M.E.	

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Includes events reported between first dose and 60 days after last dose of study therapy.
If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
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Protocol: CA204125 Page 25 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
for On-study Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (1Q21)								N.M.E.
YES	28	1 (3.6)	N.M.E.	29	5 (17.2)	N.M.E.	N.M.E.	
NO	22	0	N.M.E.	13	0	N.M.E.	N.M.E.	
NOT REPORTED	10	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

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If there are no subjects with events in E-Pd or Pd in one subgroup, display HR as n.m.e.
(1) KME of median time (2) Unstratified Cox proportional hazard model. HR is E-Pd over Pd. (3) Unstratified log-rank test.
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Protocol: CA204125 Page 26 of 26

Subgroup Time-Adjusted Analyses of Adverse Events
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All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
PT: Malignant Neoplasm Progression

Serious Adverse Events Subgroups	E-Pd N	E-Pd Patients with Event n (%)	E-Pd KME [95%CI](mon) (1)	Pd N	Pd Patients with Event n (%)	Pd KME [95%CI](mon) (1)	E-Pd vs. Pd HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
INDIVIDUAL FISH ABNORMALITIES (DEL(1P))								N.M.E.
YES	2	0	N.M.E.	1	0	N.M.E.	N.M.E.	
NO	47	1 (2.1)	N.M.E.	41	5 (12.2)	N.M.E.	N.M.E.	
NOT REPORTED	11	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	

DBL - 22FEB2021, MedDRA Version: 23.0 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 60 days after last dose of study therapy.
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