Anhang 4-G

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Selinexor (Nexpovio®)

Stemline Therapeutics B.V.

Modul 4A Anhang 4-G

Selinexor in Kombination mit Bortezomib und Dexamethason für die Behandlung des Multiplen Myeloms bei erwachsenen Patienten, die zuvor mindestens eine Therapie erhalten haben

Weitere Ergebnisse und vollständige Darstellung der Subgruppenanalysen

Stand: 28.09.2022

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Abkürzungsverzeichnis

Abkürzung	Bedeutung
AESI	UE von besonderem Interesse (Adverse Event of Special Interest)
CTCAE	Common Terminology Criteria for Adverse Events
EQ-5D-5L	European Quality of Life 5 Dimension 5 Level
EU	Europäische Union
EU/GB/NA	EU inkl. Großbritannien und Nordamerika
HR	Hazard Ratio
ISS	International Staging System
KI	Konfidenzintervall
KM	Kaplan-Meier
MedDRA	Medical Dictionary for Regulatory Activities
NA	Nicht Auswertbar
OS	Overall Survival (Gesamtüberleben)
PFS	Progression-free Survival (Progressionsfreies Überleben)
PI	Proteasominhibitor
PT	Preferred Term nach MedDRA
QLQ-C30	Quality of Life Questionnaire Core 30 (Fragebogen für onkologische Patienten)
QLQ-CIPN20	Quality of Life Questionnaire Chemotherapy-induced PN (Fragebogen zur Chemotherapie-induzierten PN-Symptomatik
R-ISS	Revised International Staging System
SOC	System Organ Class nach MedDRA
SUE	Schwerwiegendes UE
SVd	Selinexor in Kombination mit Bortezomib und Dexamethason
UE	Unerwünschtes Ereignis
Vd	Bortezomib in Kombination mit Dexamethason
TTNT	Time To Next Treatment (Zeit bis zur nächsten Behandlung)

1. Weitere Ergebnisse zu Modul 4A Abschnitt 4.3.1.3.1.4 Sicherheit: KM-Kurven mit nicht signifikantem Ergebnis

1.1 KM-Kurven zu AESI mit nicht signifikantem Ergebnis

Nachfolgend werden die KM-Kurven zu den Ereigniszeitanalysen zu AESI mit nicht signifikantem Ergebnis dargestellt. Sofern aufgrund zu geringer Ereigniszahlen die Cox-Regression nicht interpretierbar war, werden keine KM-Kurven dargestellt. Dies betrifft die schweren AESI Übelkeit, Erbrechen, Verminderter Appetit, getrübte Sicht und die schwerwiegenden AESI Übelkeit, Erbrechen, Verminderter Appetit, Gewichtsverlust, getrübte Sicht, Katarakt und Hyponatriämie.

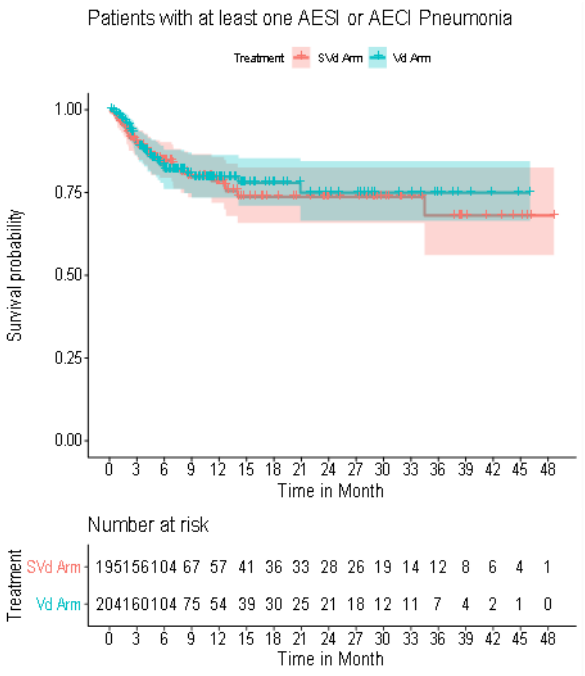

Abbildung 1: Kaplan-Meier-Kurven zu AESI Pneumonie unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

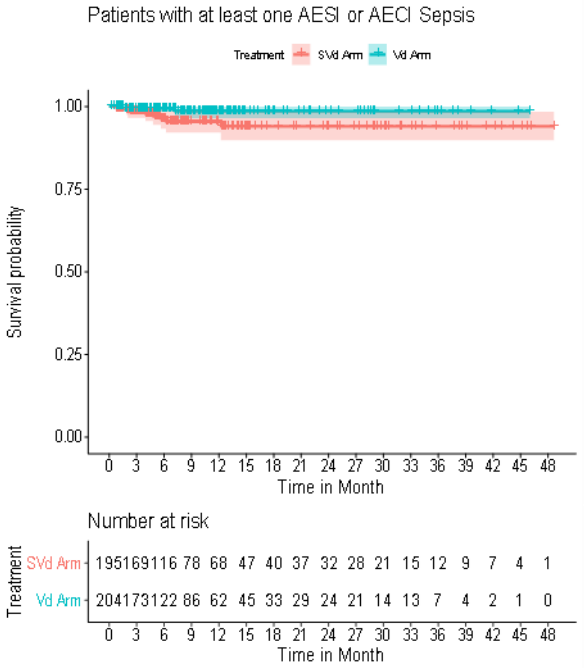

Abbildung 2: Kaplan-Meier-Kurven zu AESI Sepsis unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

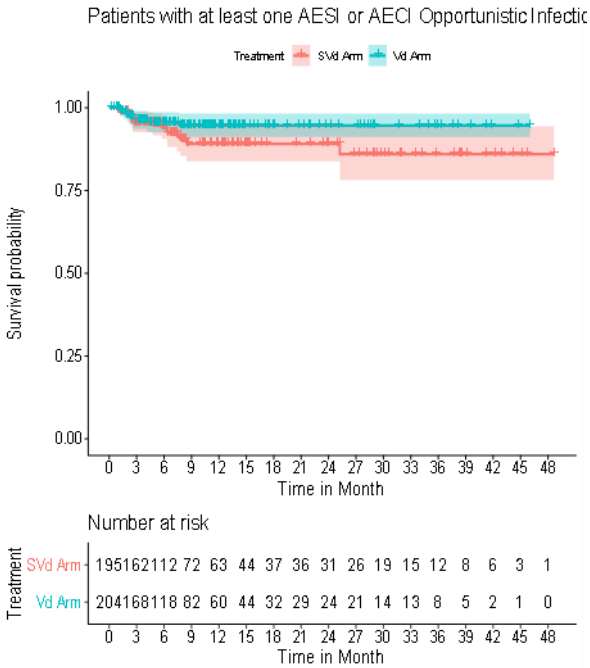

Abbildung 3: Kaplan-Meier-Kurven zu AESI opportunistische Infektionen unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

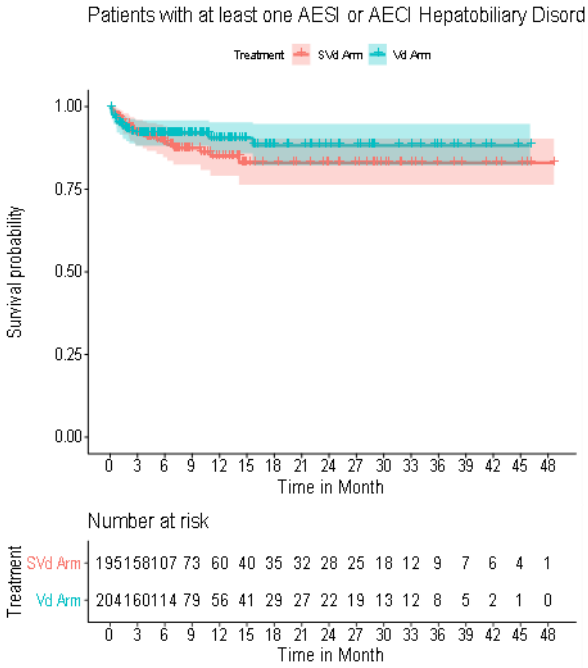

Abbildung 4: Kaplan-Meier-Kurven zu AESI Hepatobiliäre Störungen unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

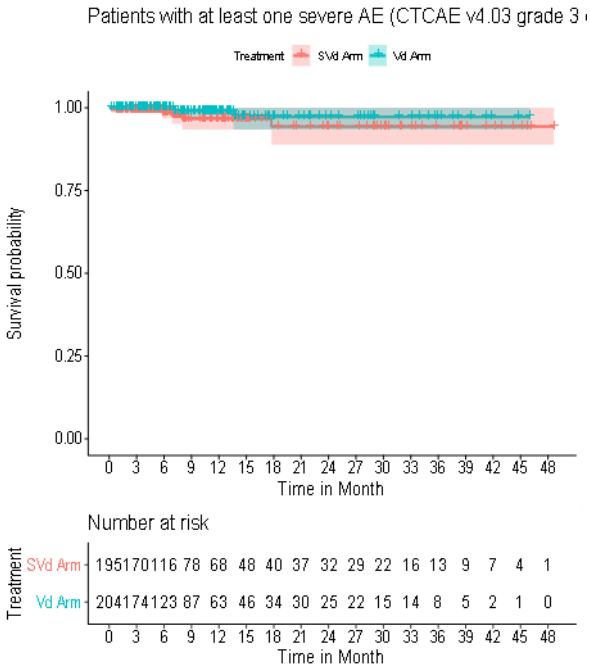

Abbildung 5: Kaplan-Meier-Kurven zu schweren AESI Gewichtsverlust (CTCAE v4.03 Grad ≥ 3)

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

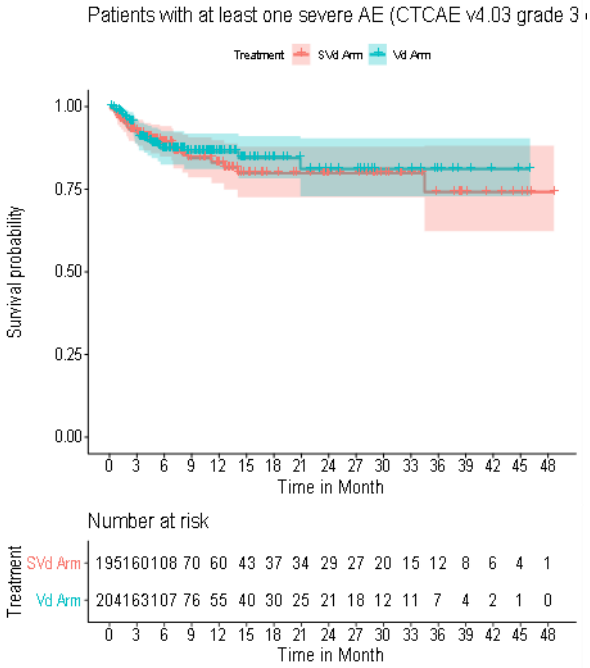

Abbildung 6: Kaplan-Meier-Kurven zu schweren AESI Pneumonie (CTCAE v4.03 Grad ≥ 3)
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

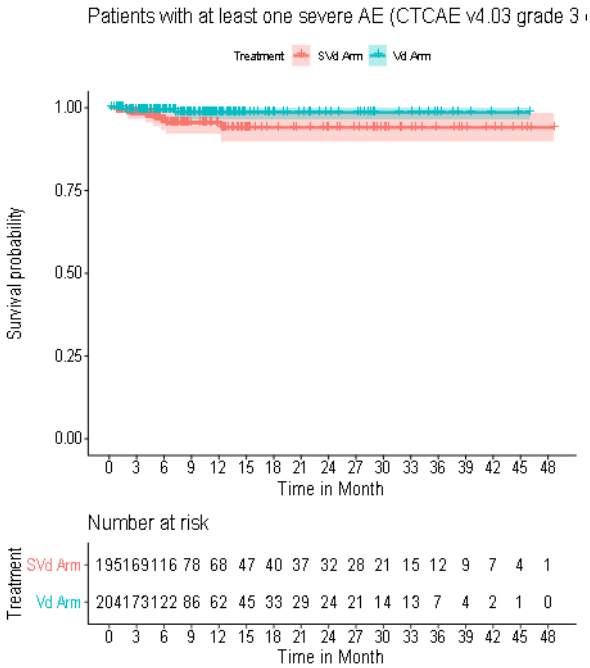

Abbildung 7: Kaplan-Meier-Kurven zu schweren AESI Sepsis (CTCAE v4.03 Grad ≥ 3)
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

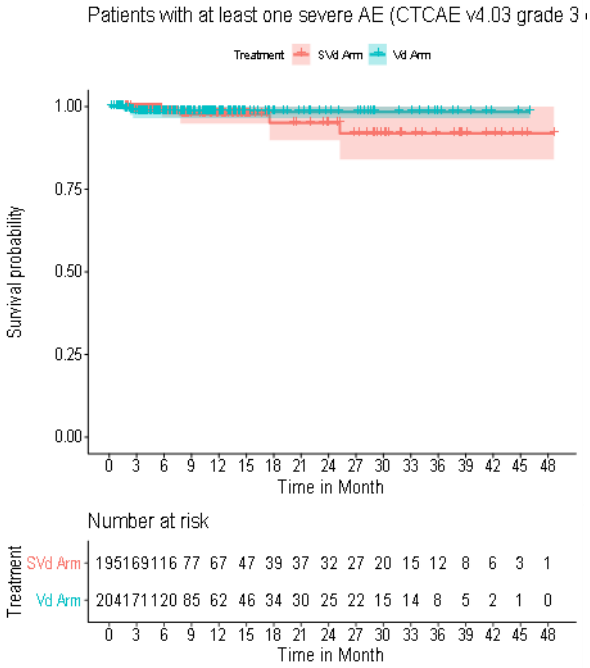

Abbildung 8: Kaplan-Meier-Kurven zu schweren AESI Opportunistische Infektionen (CTCAE v4.03 Grad ≥ 3)

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

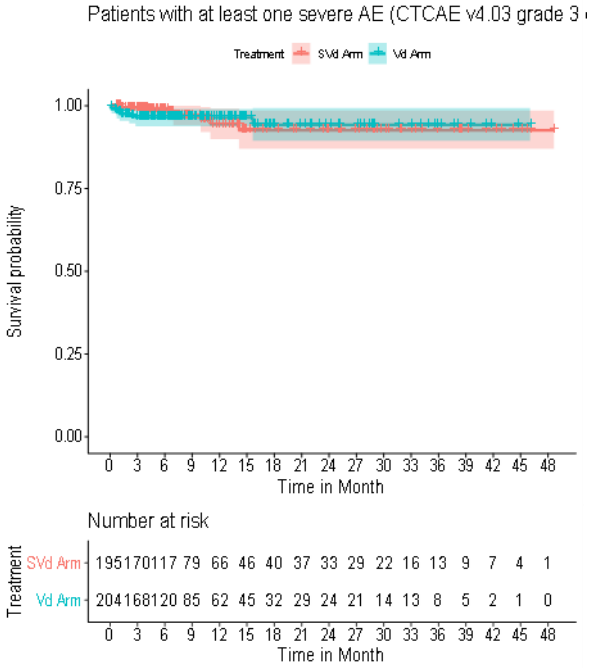

Abbildung 9: Kaplan-Meier-Kurven zu schweren AESI Hepatobiliäre Störungen (CTCAE v4.03 Grad ≥ 3)

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

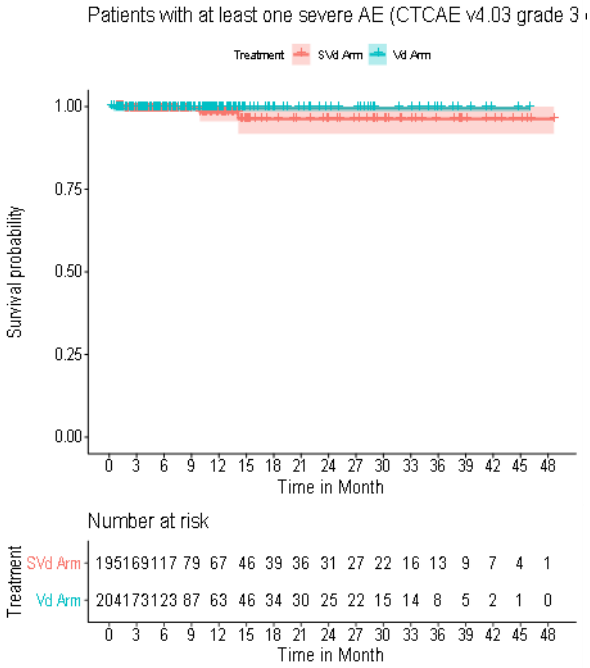

Abbildung 10: Kaplan-Meier-Kurven zu schweren AESI Kardiotoxizität (CTCAE v4.03 Grad ≥ 3)

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

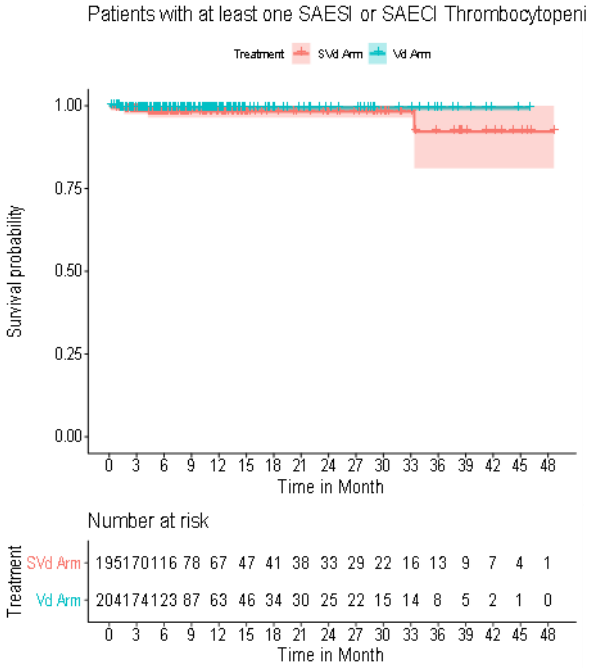

Abbildung 11: Kaplan-Meier-Kurven zu schwerwiegenden AESI Thrombozytopenie

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

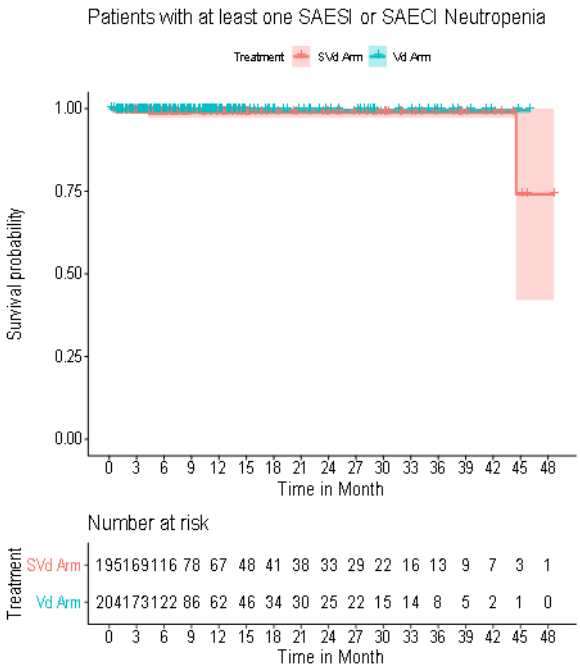

Abbildung 12: Kaplan-Meier-Kurven zu schwerwiegenden AESI Neutropenie

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

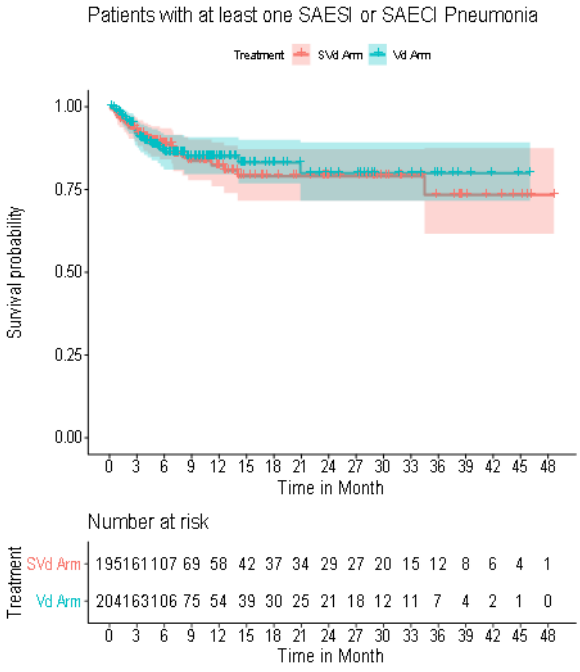

Abbildung 13: Kaplan-Meier-Kurven zu schwerwiegenden AESI Pneumonie

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

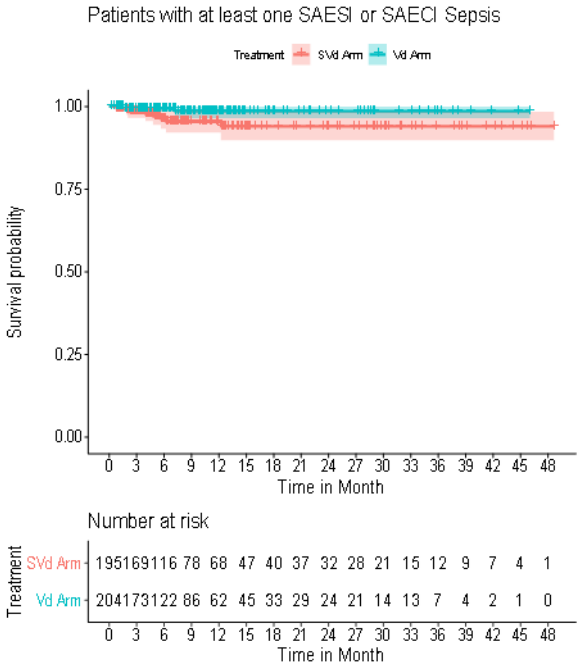

Abbildung 14: Kaplan-Meier-Kurven zu schwerwiegenden AESI Sepsis

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

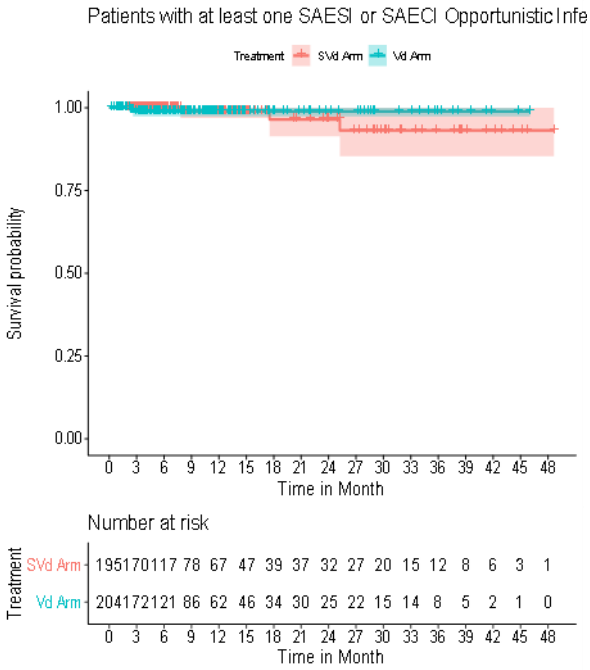

Abbildung 15: Kaplan-Meier-Kurven zu schwerwiegenden AESI Opportunistische Infektionen

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

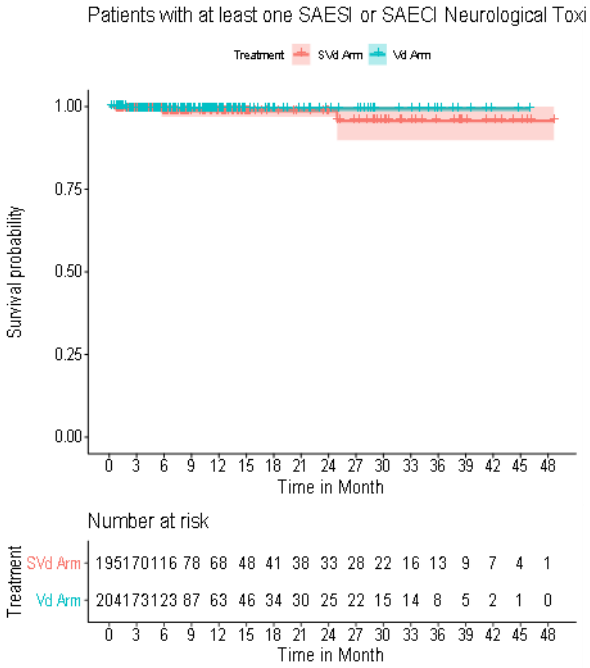

Abbildung 16: Kaplan-Meier-Kurven zu schwerwiegenden AESI Neurotoxizität

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

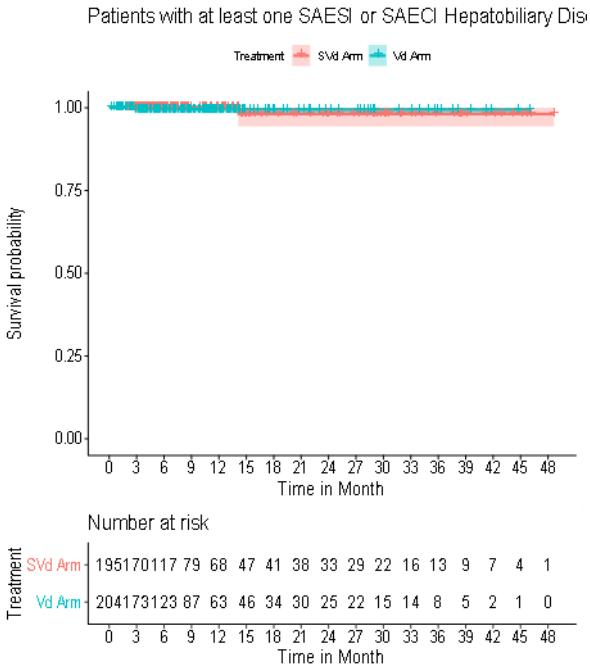

Abbildung 17: Kaplan-Meier-Kurven zu schwerwiegenden AESI Heptatobiliäre Störungen

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

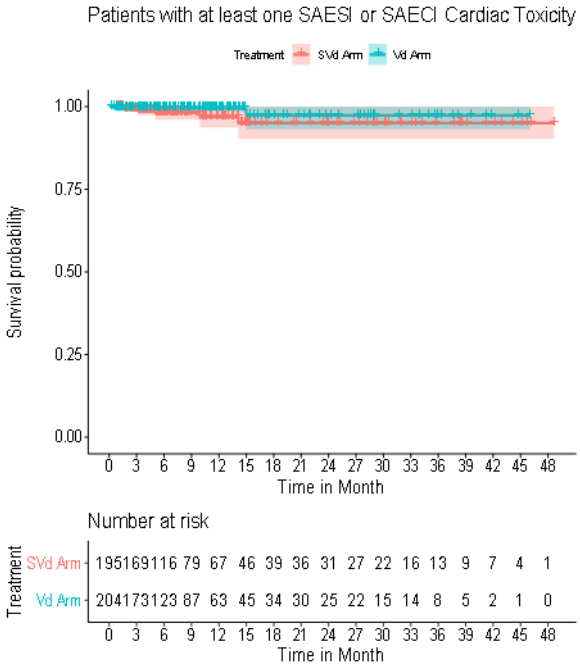

Abbildung 18: Kaplan-Meier-Kurven zu schwerwiegenden AESI Kardiotoxizität

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

1.2 KM-Kurven zu UE nach SOC und PT mit nicht signifikantem Ergebnis

Nachfolgend werden die KM-Kurven zu den Ereigniszeitanalysen zu UE nach SOC und PT mit nicht signifikantem Ergebnis dargestellt. Sofern aufgrund zu geringer Ereigniszahlen die Cox-Regression nicht interpretierbar war, werden keine KM-Kurven dargestellt. Dies betrifft das UE nach SOC und PT Überdosis unabhängig vom Schweregrad und das schwere UE nach SOC und PT Übelkeit.

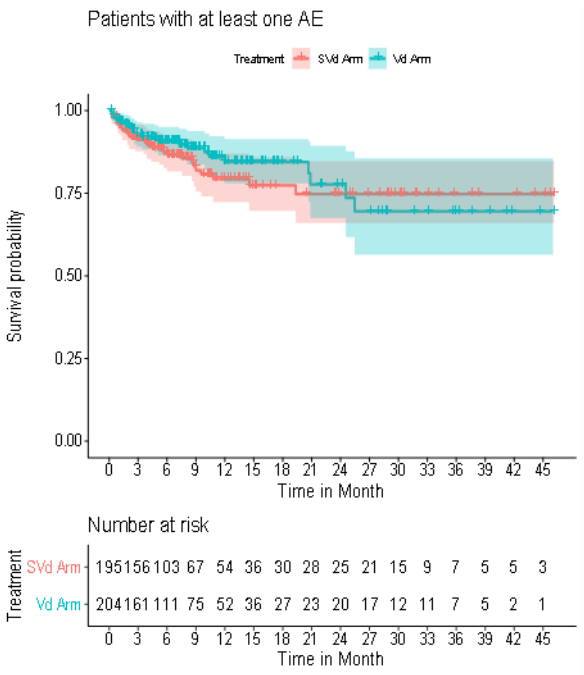

Abbildung 19: Kaplan-Meier-Kurven zu PT Fieber unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

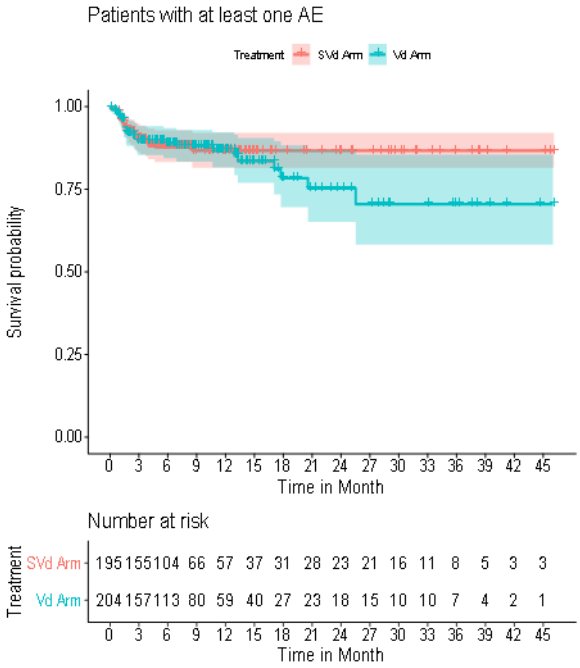

Abbildung 20: Kaplan-Meier-Kurven zu PT Ödem peripher unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

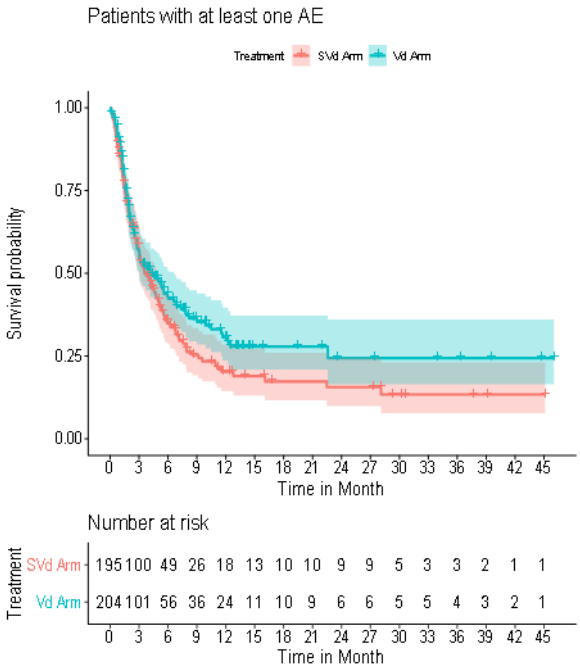

Abbildung 21: Kaplan-Meier-Kurven zu SOC Infektionen und parasitäre Erkrankungen unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

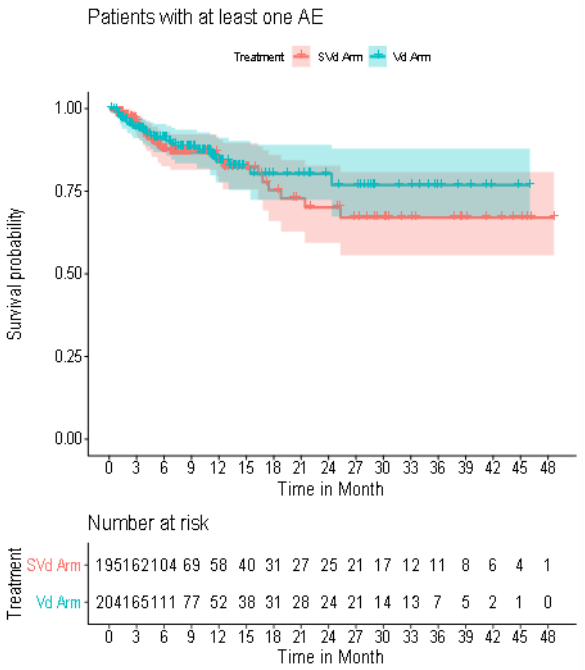

Abbildung 22: Kaplan-Meier-Kurven zu PT Infektion der oberen Atemwege unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

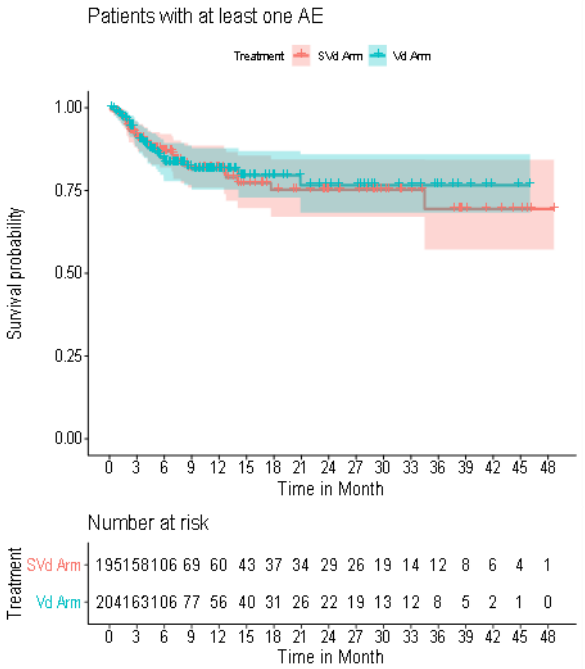

Abbildung 23: Kaplan-Meier-Kurven zu PT Pneumonie unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

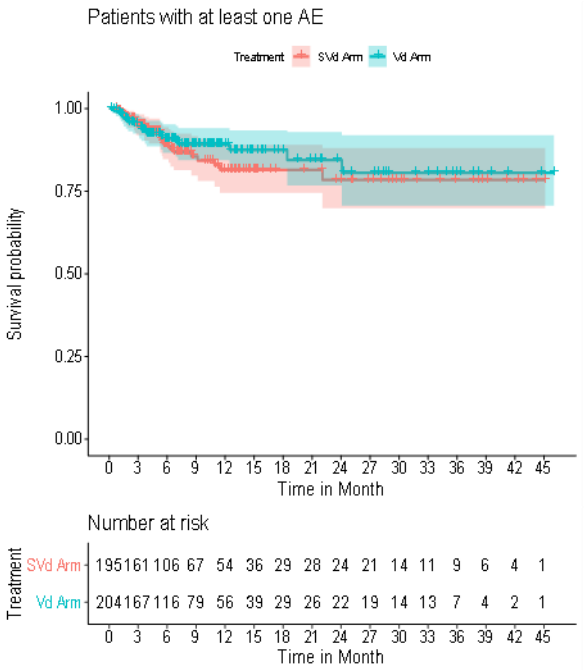

Abbildung 24: Kaplan-Meier-Kurven zu PT Bronchitis unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

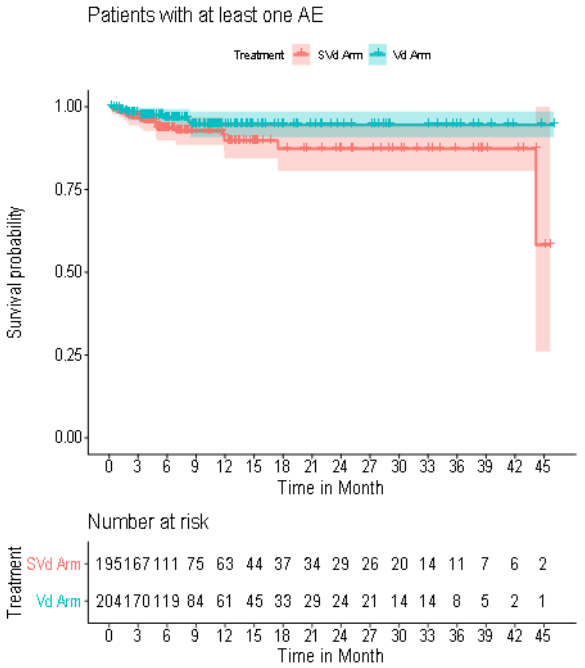

Abbildung 25: Kaplan-Meier-Kurven zu PT Atemwegsinfektion unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

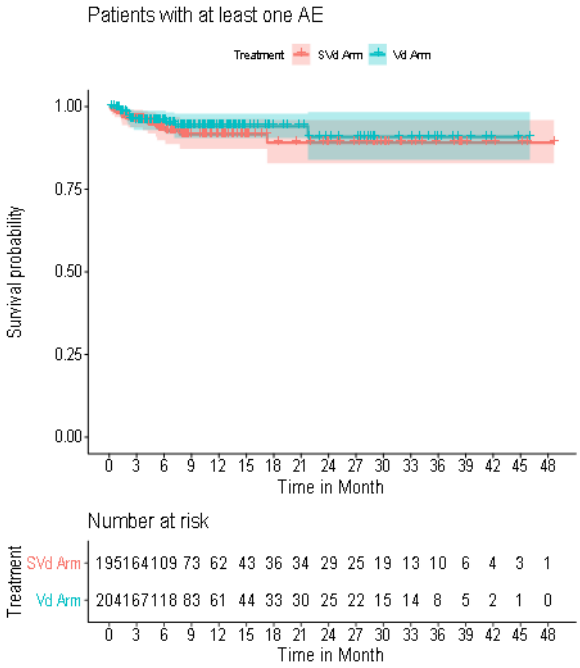

Abbildung 26: Kaplan-Meier-Kurven zu PT Infektion der unteren Atemwege unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

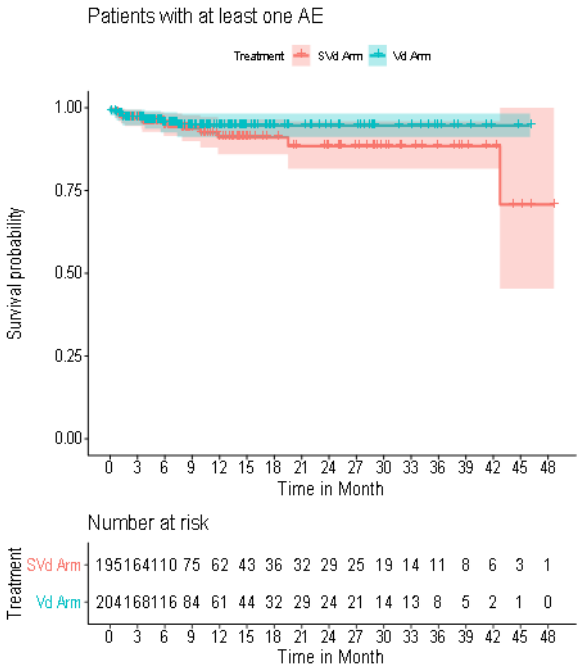

Abbildung 27: Kaplan-Meier-Kurven zu PT Harnwegsinfektion unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

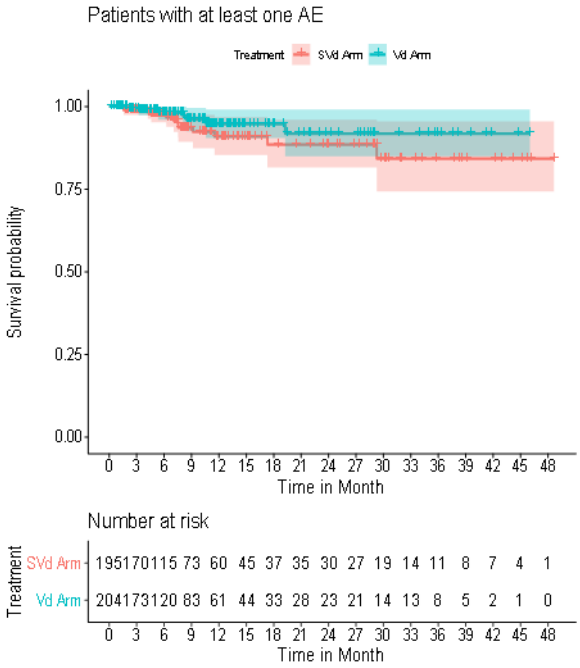

Abbildung 28: Kaplan-Meier-Kurven zu PT Grippe unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

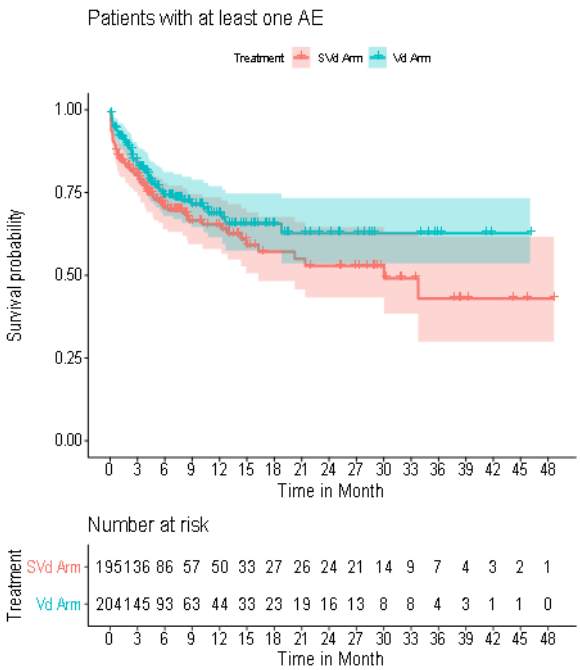

Abbildung 29: Kaplan-Meier-Kurven zu PT Diarrhö unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

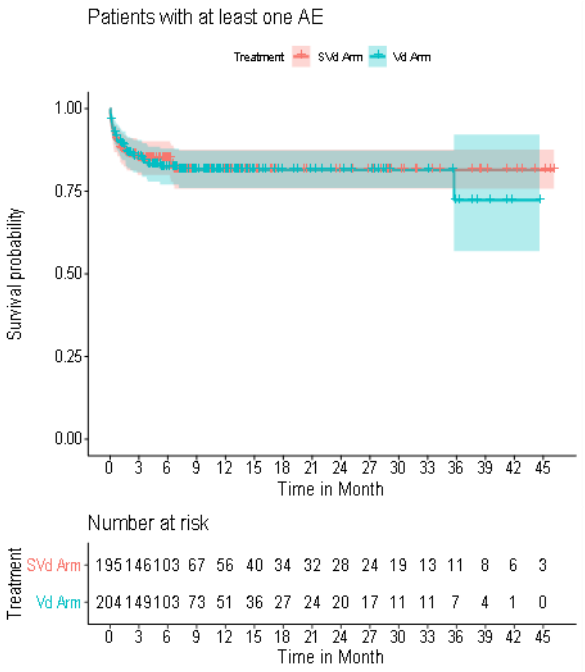

Abbildung 30: Kaplan-Meier-Kurven zu PT Obstipation unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

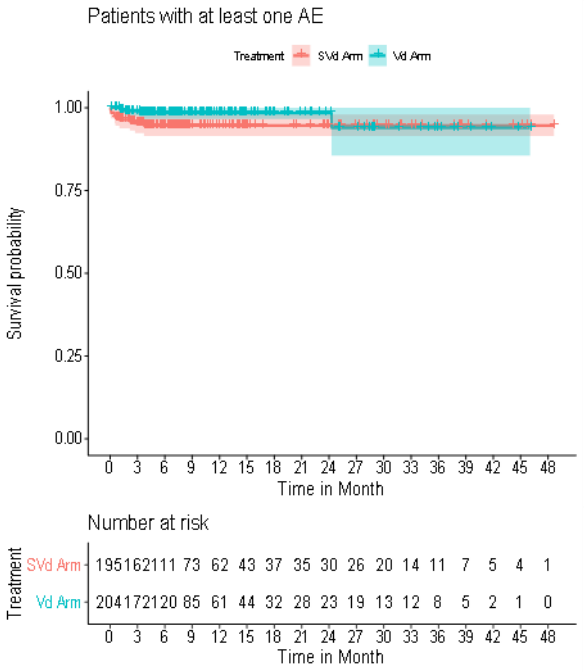

Abbildung 31: Kaplan-Meier-Kurven zu PT Abdominalschmerz unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

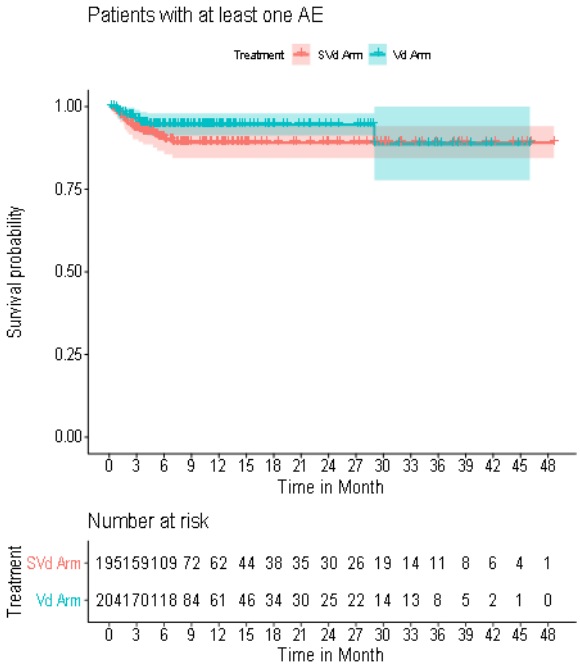

Abbildung 32: Kaplan-Meier-Kurven zu PT Hypokaliämie unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

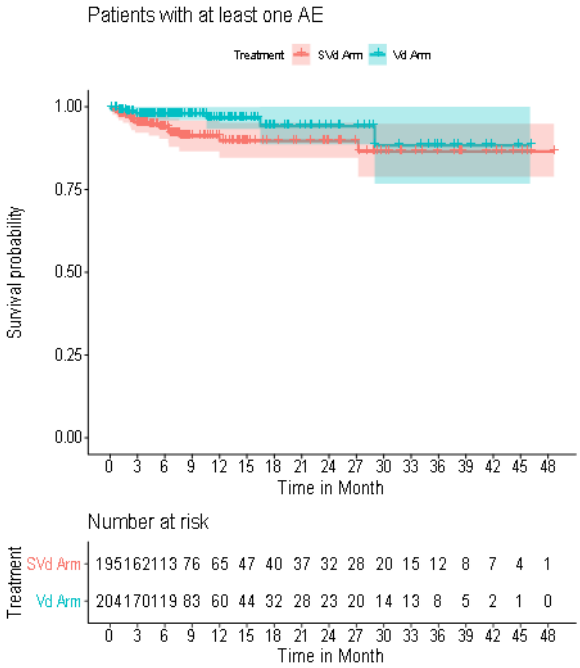

Abbildung 33: Kaplan-Meier-Kurven zu PT Hypophosphatämie unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

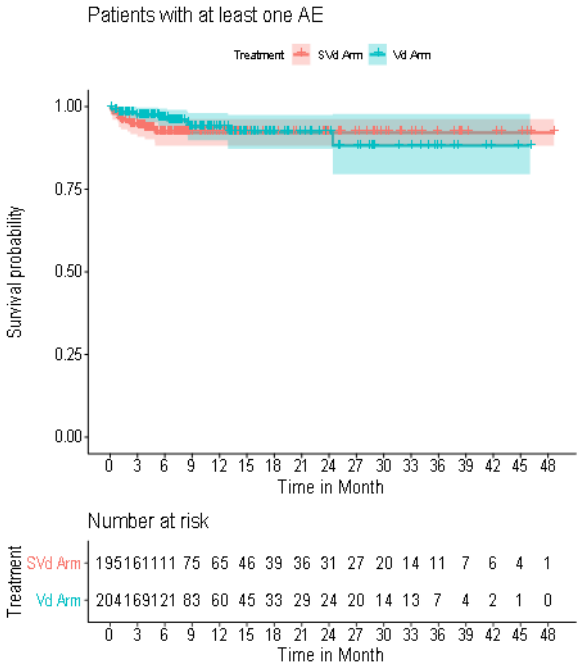

Abbildung 34: Kaplan-Meier-Kurven zu PT Hyperglykämie unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

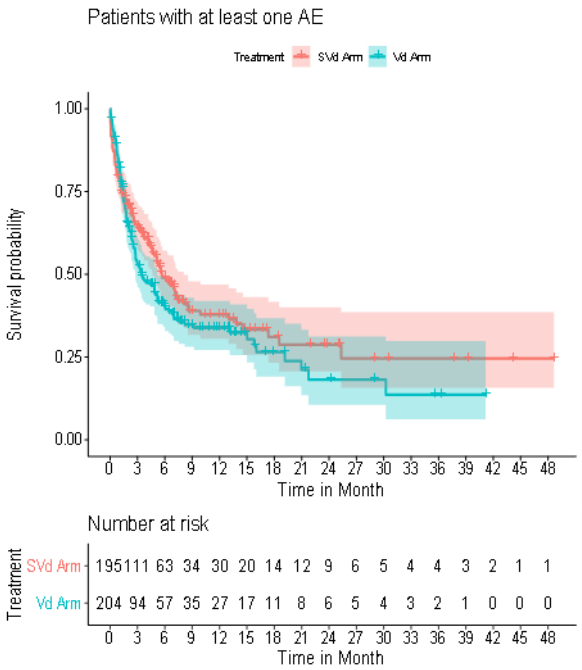

Abbildung 35: Kaplan-Meier-Kurven zu SOC Erkrankungen des Nervensystems unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

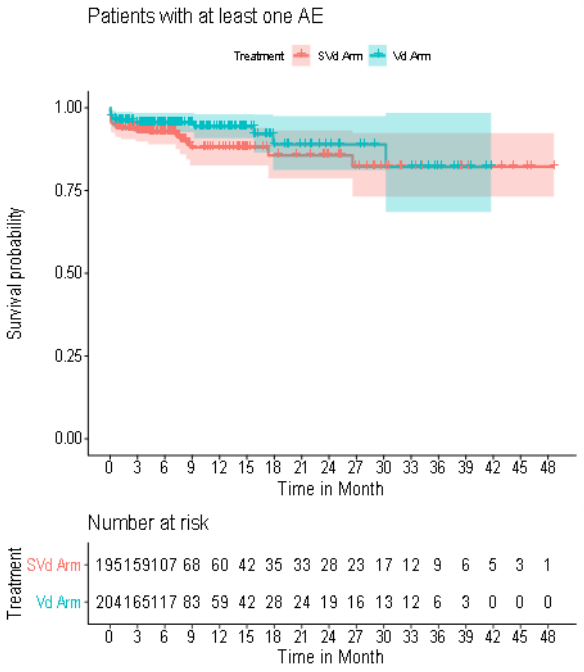

Abbildung 36: Kaplan-Meier-Kurven zu PT Kopfschmerzen unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

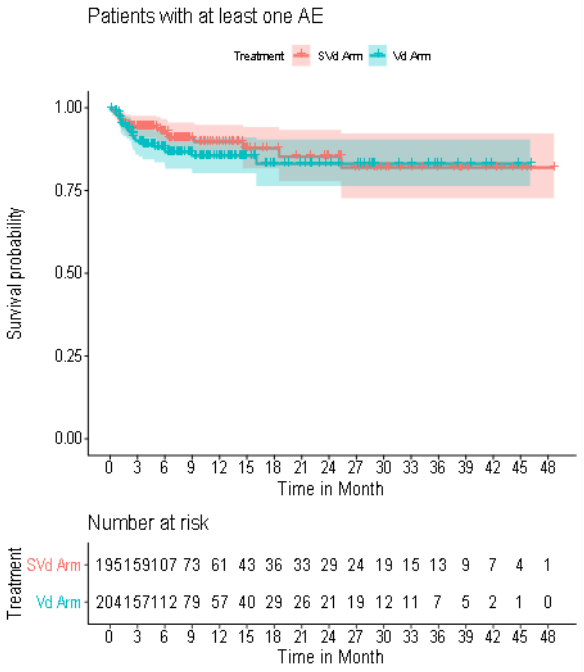

Abbildung 37: Kaplan-Meier-Kurven zu PT Periphere sensorische Neuropathie unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

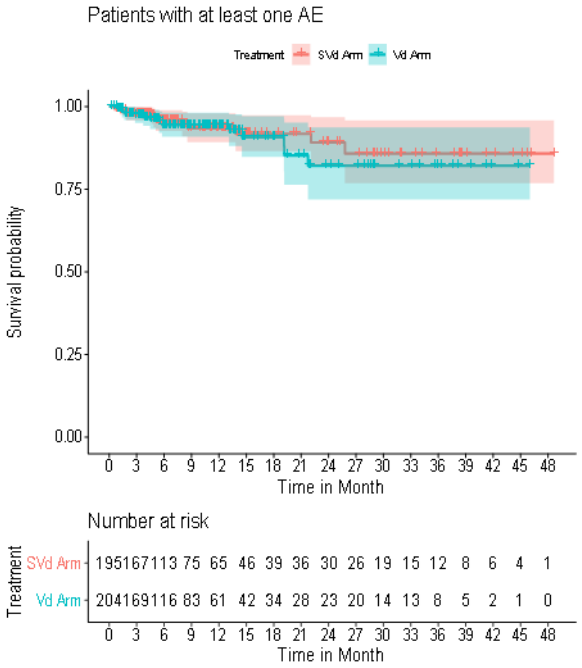

Abbildung 38: Kaplan-Meier-Kurven zu PT Polyneuropathie unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

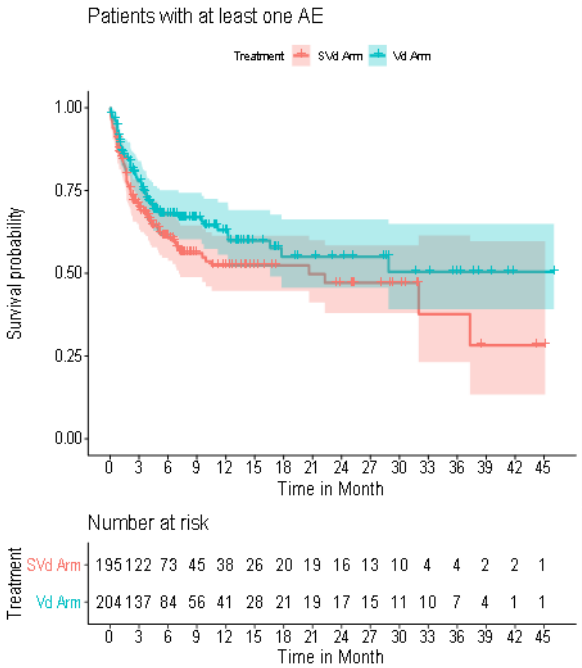

Abbildung 39: Kaplan-Meier-Kurven zu SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

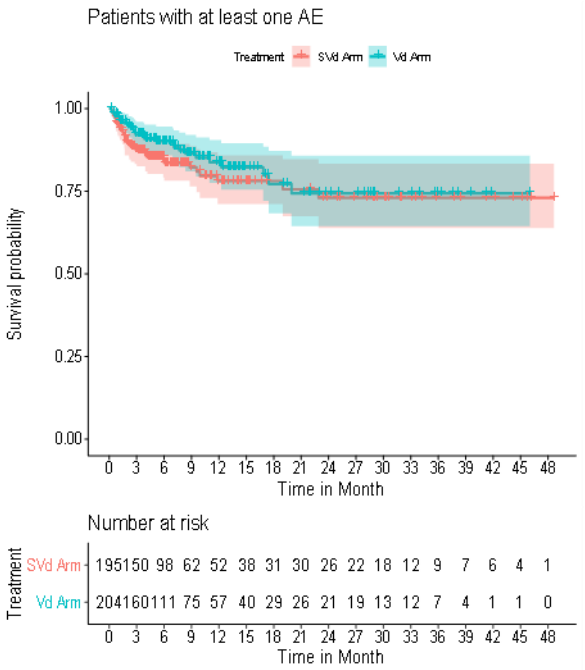

Abbildung 40: Kaplan-Meier-Kurven zu PT Husten unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

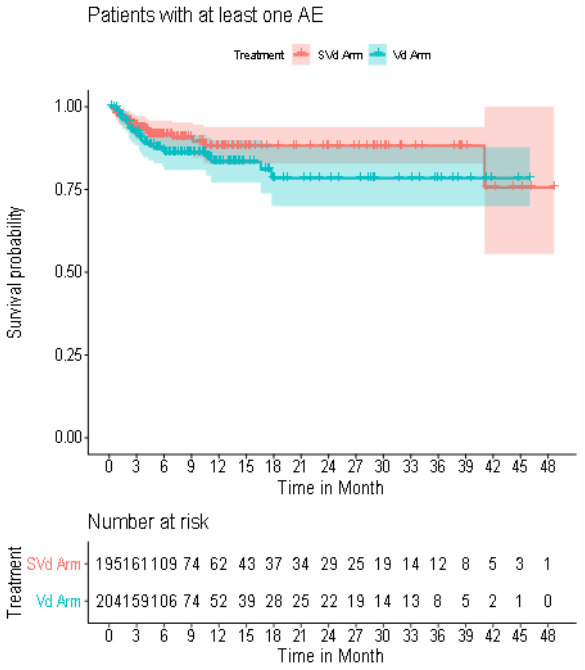

Abbildung 41: Kaplan-Meier-Kurven zu PT Dyspnoe unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

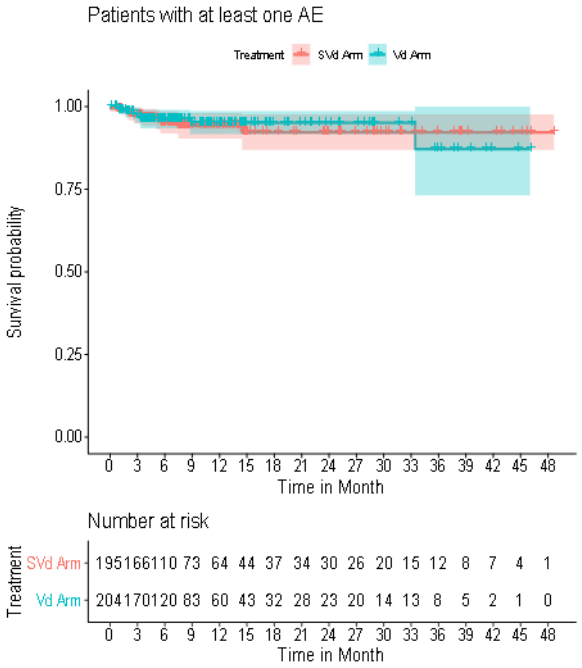

Abbildung 42: Kaplan-Meier-Kurven zu PT Belastungsdyspnoe unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

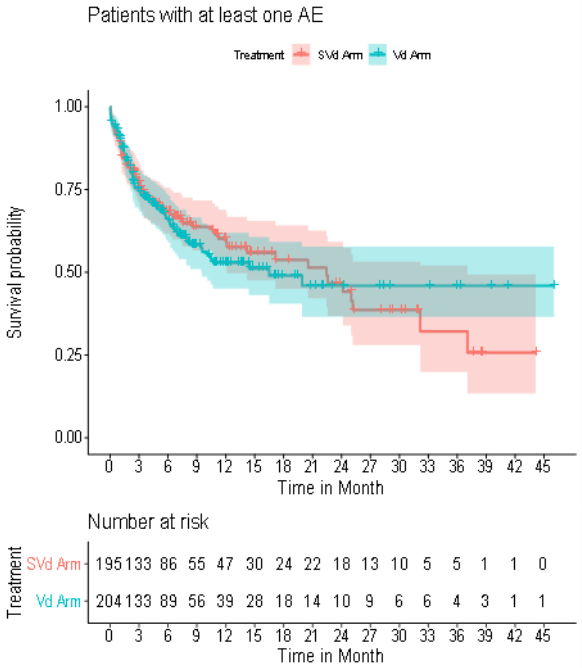

Abbildung 43: Kaplan-Meier-Kurven zu SOC Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen unabhängig vom Schweregrad
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

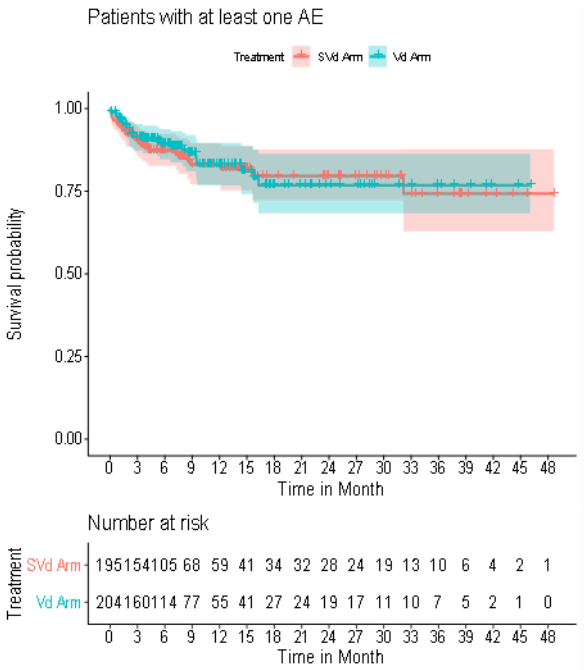

Abbildung 44: Kaplan-Meier-Kurven zu PT Rückenschmerzen unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

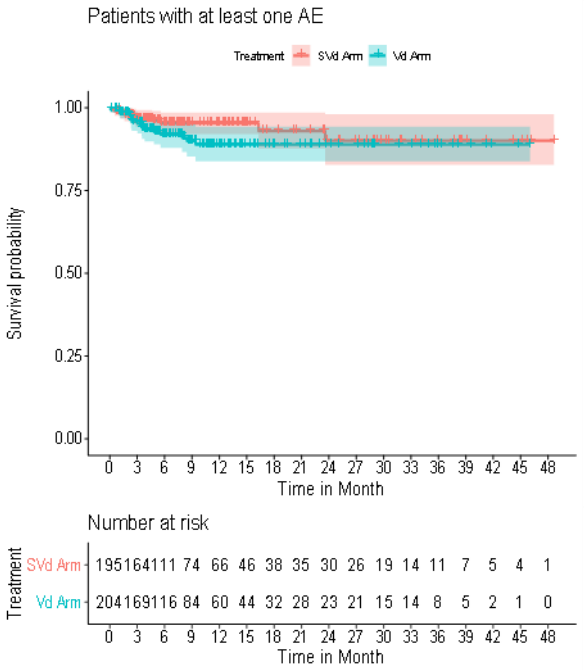

Abbildung 45: Kaplan-Meier-Kurven zu Schmerzen in einer Extremität unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

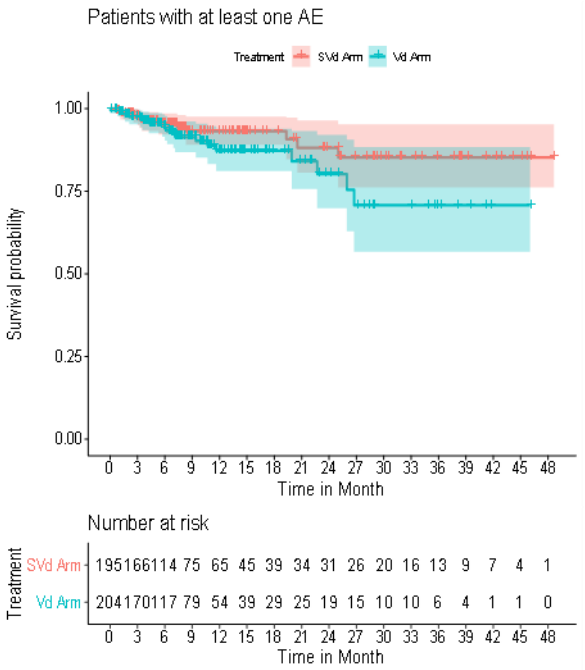

Abbildung 46: Kaplan-Meier-Kurven zu PT Arthralgie unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

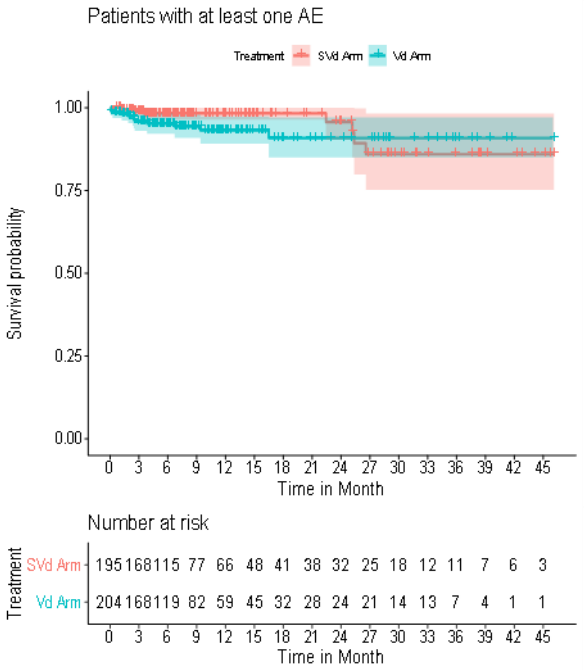

Abbildung 47: Kaplan-Meier-Kurven zu PT Muskelspasmen unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

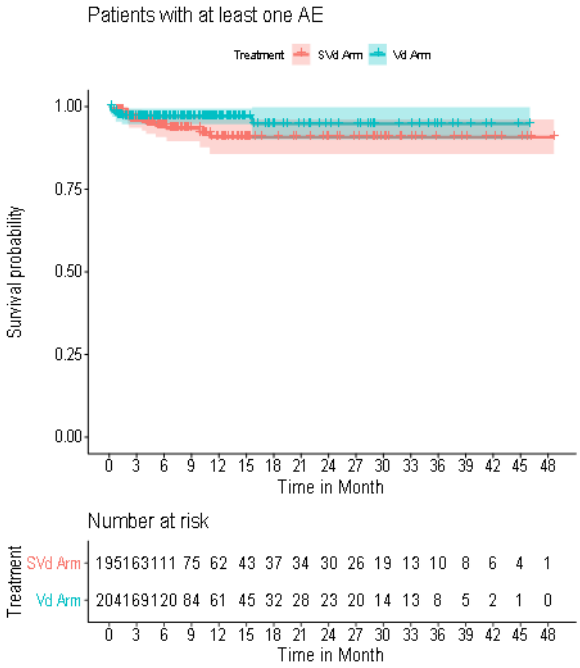

Abbildung 48: Kaplan-Meier-Kurven zu PT Alanintransferase erhöht unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

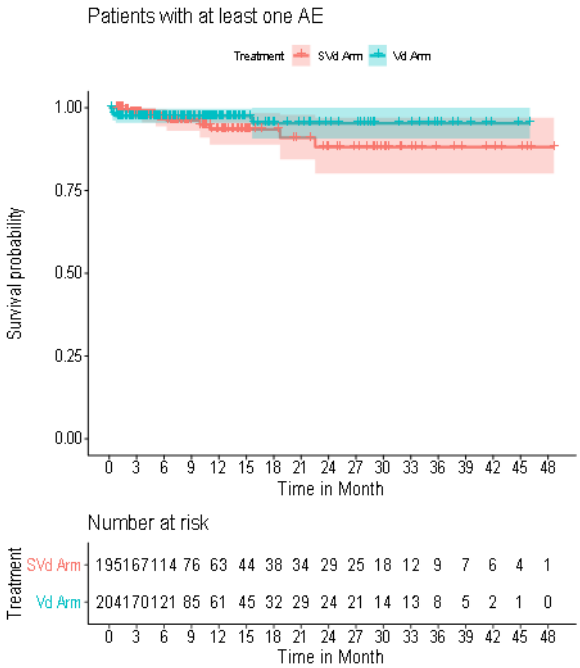

Abbildung 49: Kaplan-Meier-Kurven zu PT Aspartataminotransferase erhöht unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

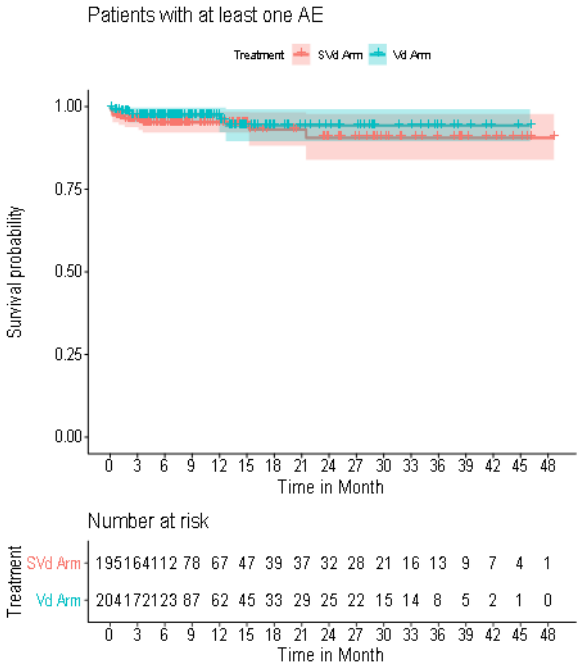

Abbildung 50: Kaplan-Meier-Kurven zu PT Kreatinin im Blut erhöht unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

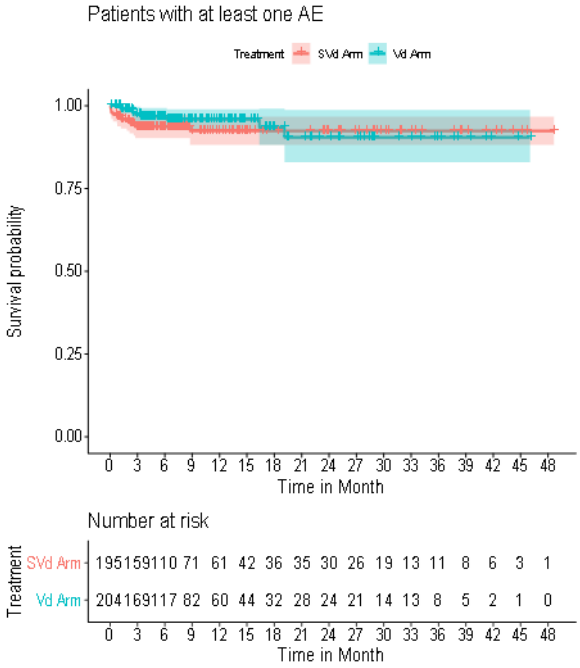

Abbildung 51: Kaplan-Meier-Kurven zu PT Sehen verschwommen unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

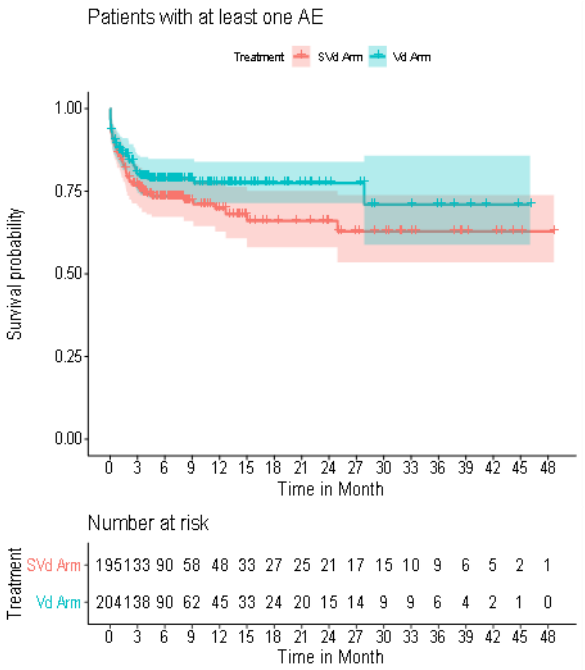

Abbildung 52: Kaplan-Meier-Kurven zu SOC Psychiatrische Erkrankungen unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

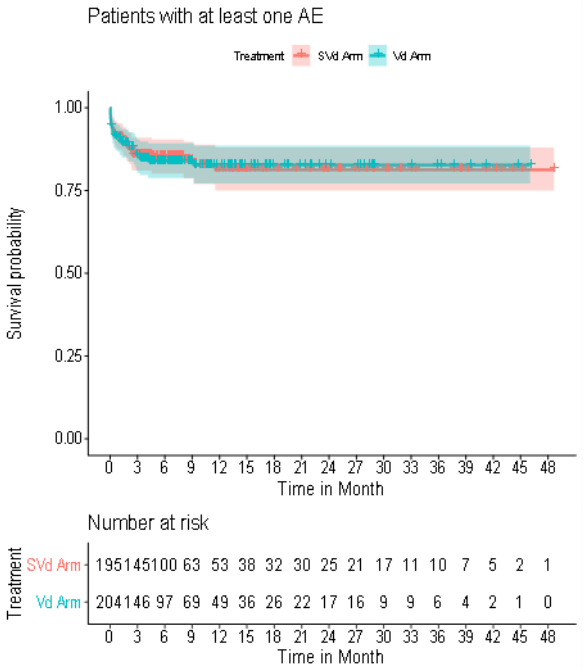

Abbildung 53: Kaplan-Meier-Kurven zu PT Schlaflosigkeit unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

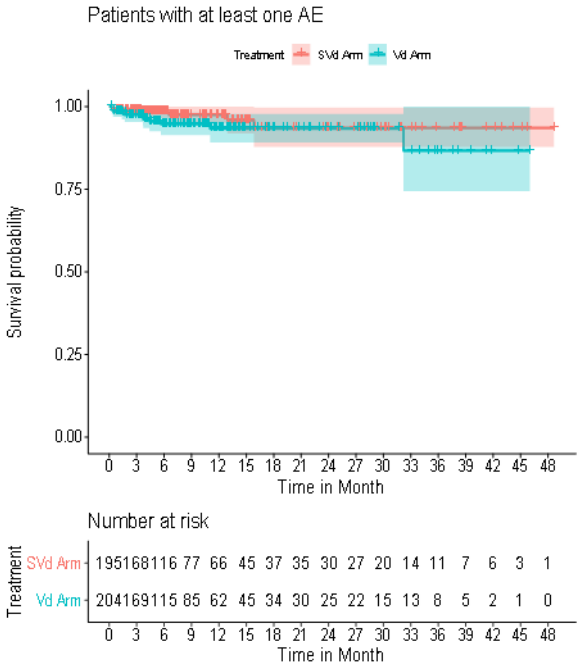

Abbildung 54: Kaplan-Meier-Kurven zu PT Ausschlag unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

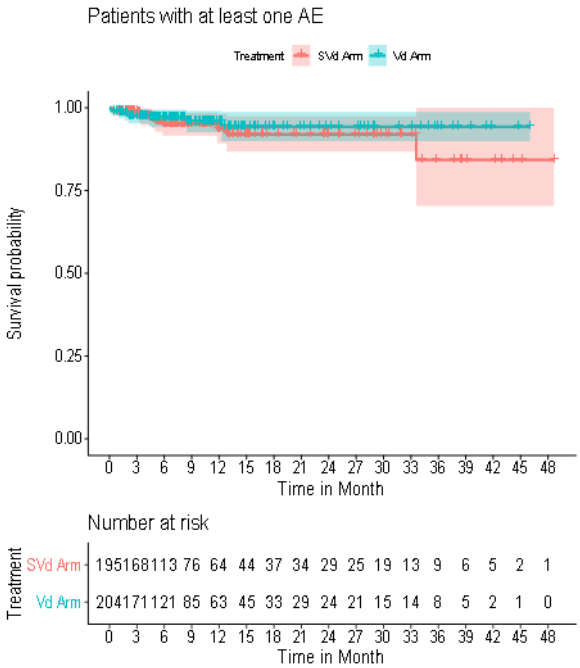

Abbildung 55: Kaplan-Meier-Kurven zu PT Sturz unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

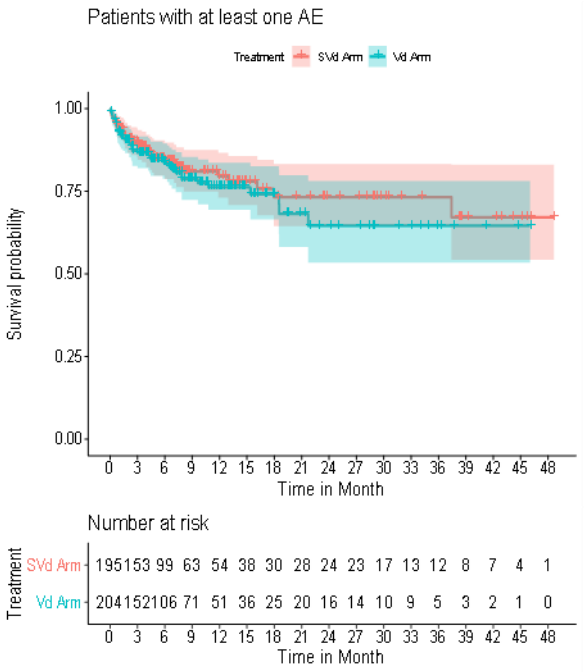

Abbildung 56: Kaplan-Meier-Kurven zu SOC Gefäßerkrankungen unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

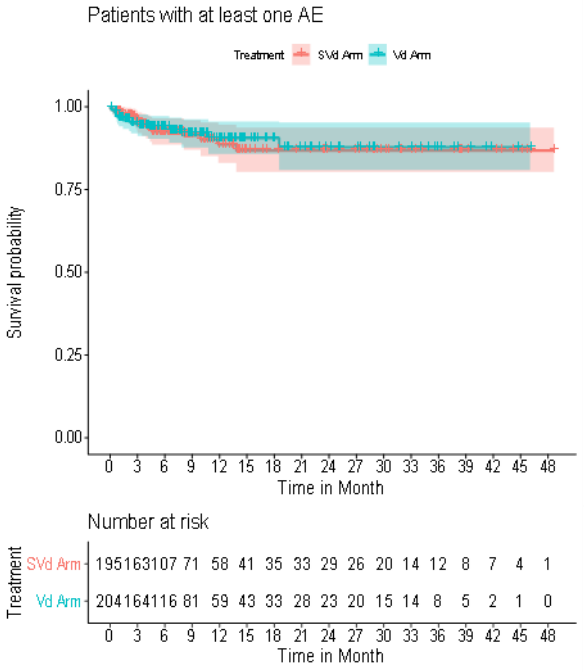

Abbildung 57: Kaplan-Meier-Kurven zu PT Hypertonie unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

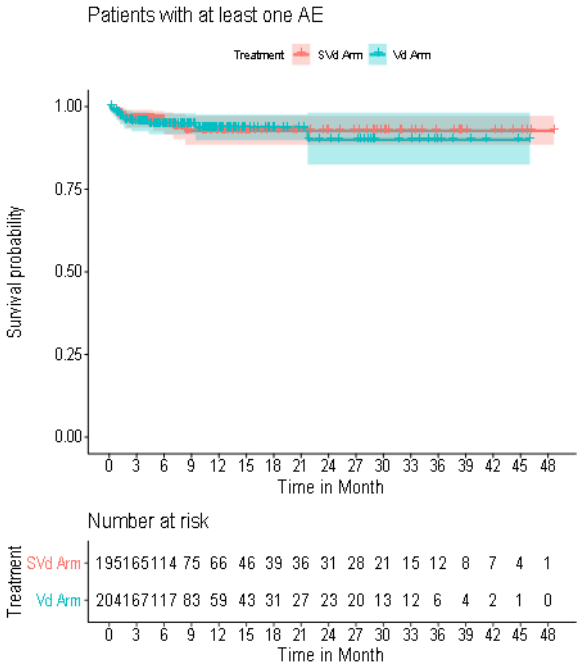

Abbildung 58: Kaplan-Meier-Kurven zu PT Hypotonie unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

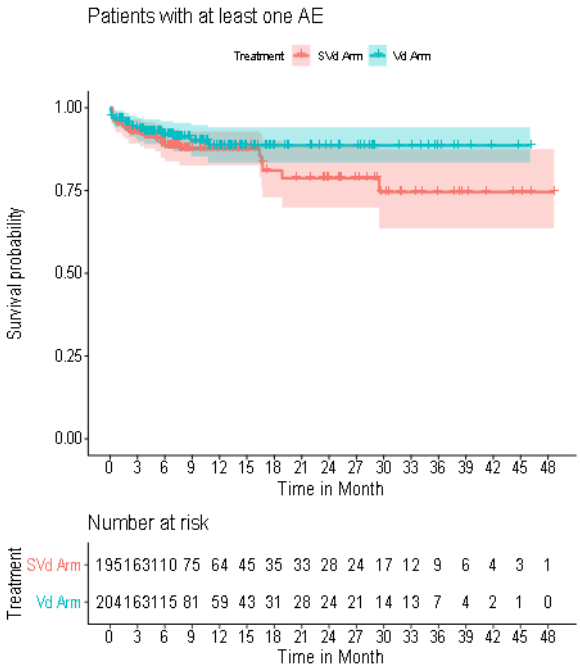

Abbildung 59: Kaplan-Meier-Kurven zu SOC Erkrankungen der Nieren und Harnwege unabhängig vom Schweregrad

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

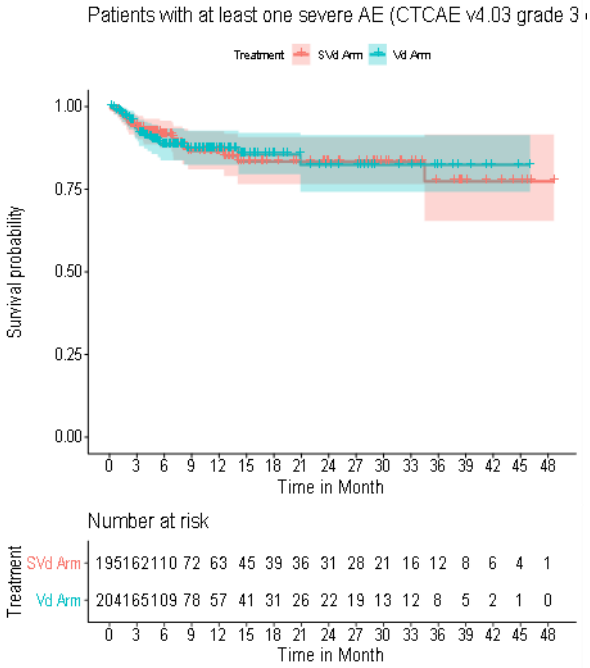

Abbildung 60: Kaplan-Meier-Kurven zu schweren (CTCAE v4.03 Grad ≥ 3) PT Pneumonie
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

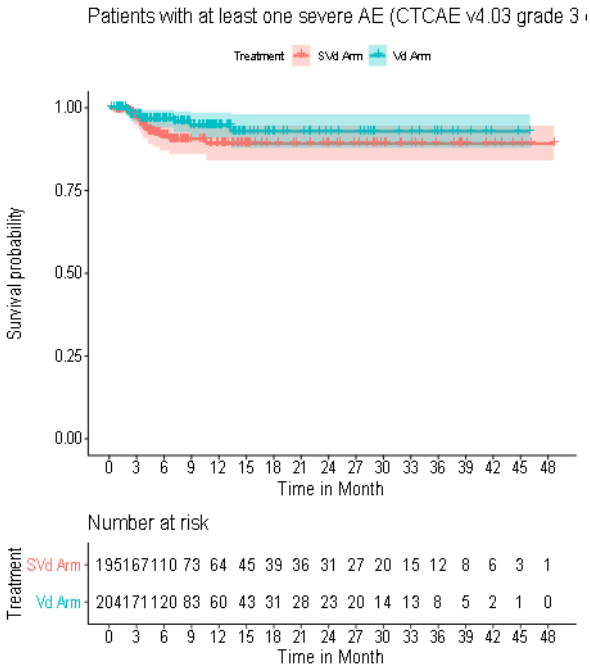

Abbildung 61: Kaplan-Meier-Kurven zu schweren (CTCAE v4.03 Grad ≥ 3) PT Asthenie
SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

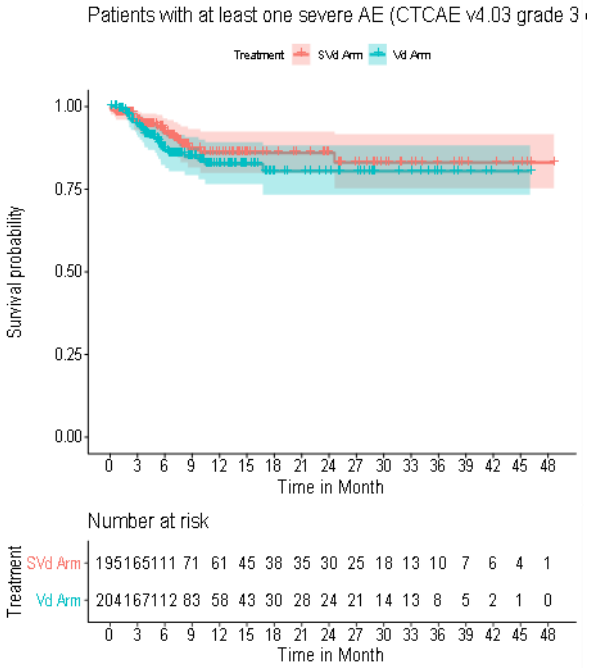

Abbildung 62: Kaplan-Meier-Kurven zu schweren (CTCAE v4.03 Grad ≥ 3) SOC Erkrankungen des Nervensystems

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

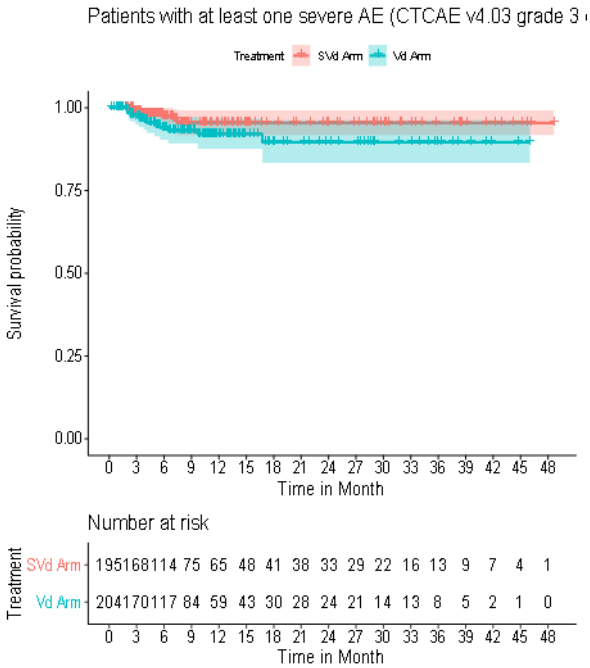

Abbildung 63: Kaplan-Meier-Kurven zu schweren (CTCAE v4.03 Grad ≥ 3) PT Periphere Neuropathie

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

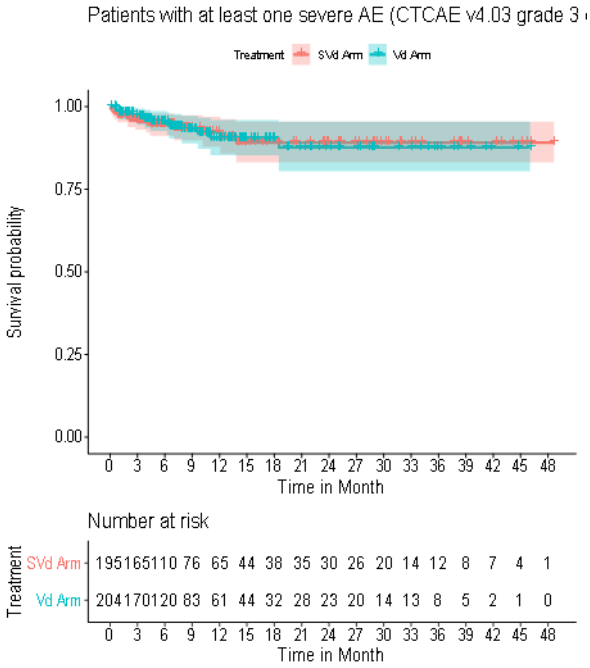

Abbildung 64: Kaplan-Meier-Kurven zu schweren (CTCAE v4.03 Grad ≥ 3) SOC Gefäßerkrankungen

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

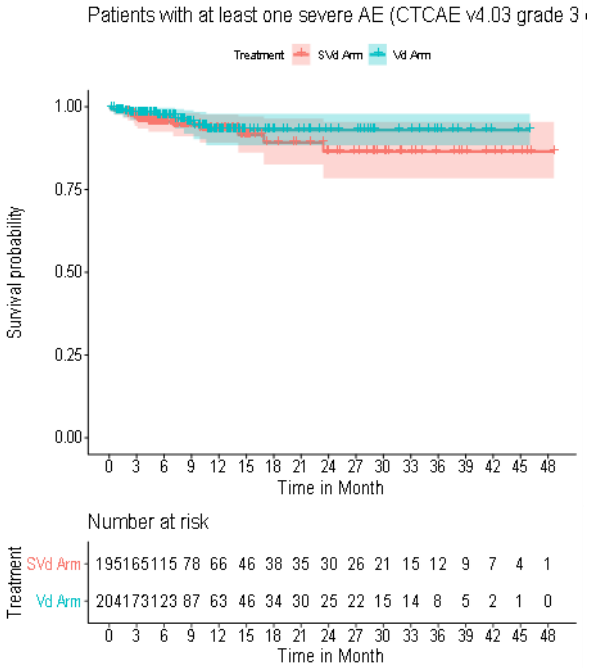

Abbildung 65: Kaplan-Meier-Kurven zu schweren (CTCAE v4.03 Grad ≥ 3) SOC Herzerkrankungen

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

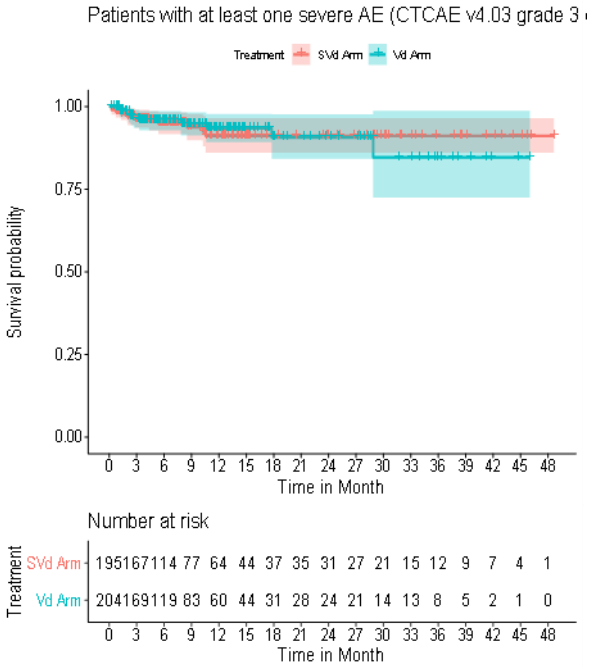

Abbildung 66: Kaplan-Meier-Kurven zu schweren (CTCAE v4.03 Grad ≥ 3) SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

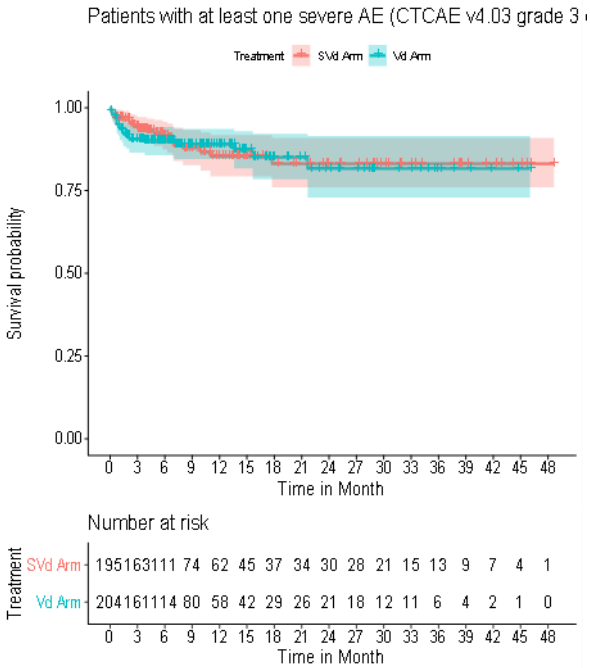

Abbildung 67: Kaplan-Meier-Kurven zu schweren (CTCAE v4.03 Grad ≥ 3) SOC Untersuchungen

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

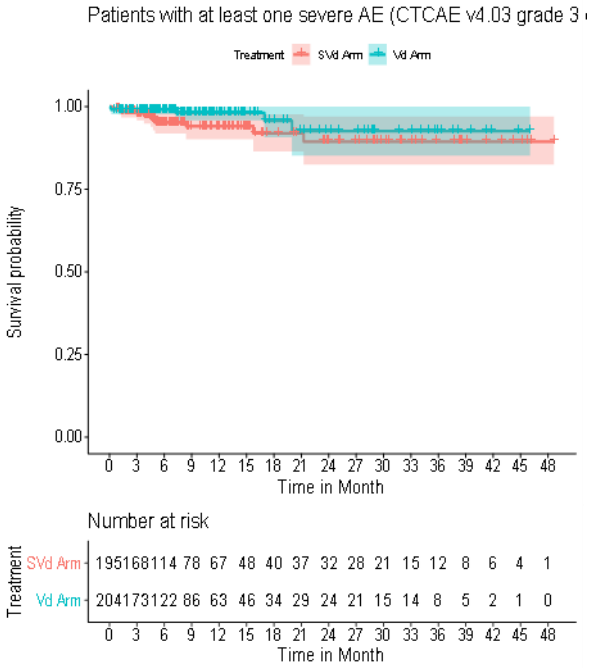

Abbildung 68: Kaplan-Meier-Kurven zu schweren (CTCAE v4.03 Grad ≥ 3) SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

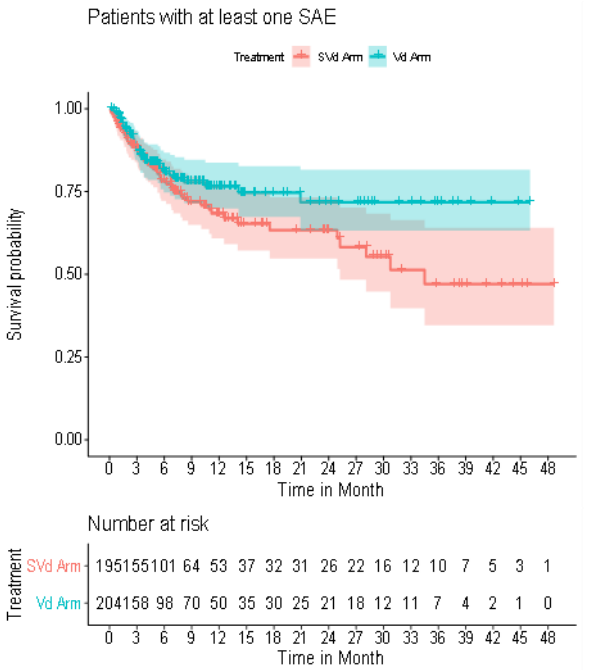

Abbildung 69: Kaplan-Meier-Kurven zu SUE SOC Infektionen und parasitäre Erkrankungen

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

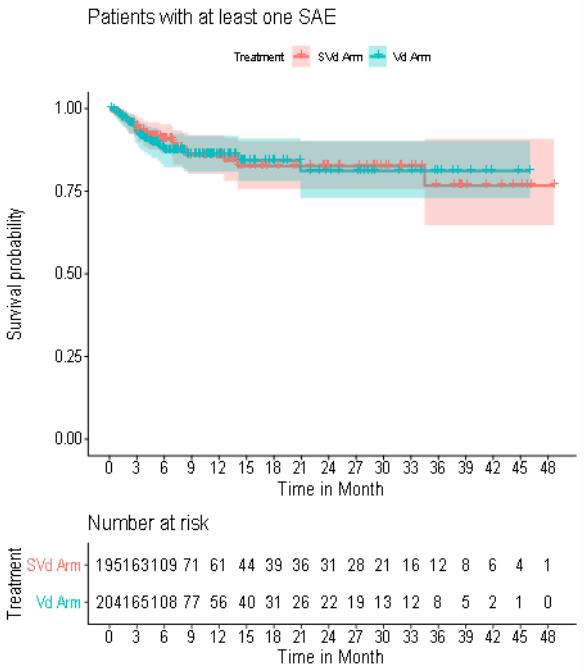

Abbildung 70: Kaplan-Meier-Kurven zu SUE PT Pneumonie

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

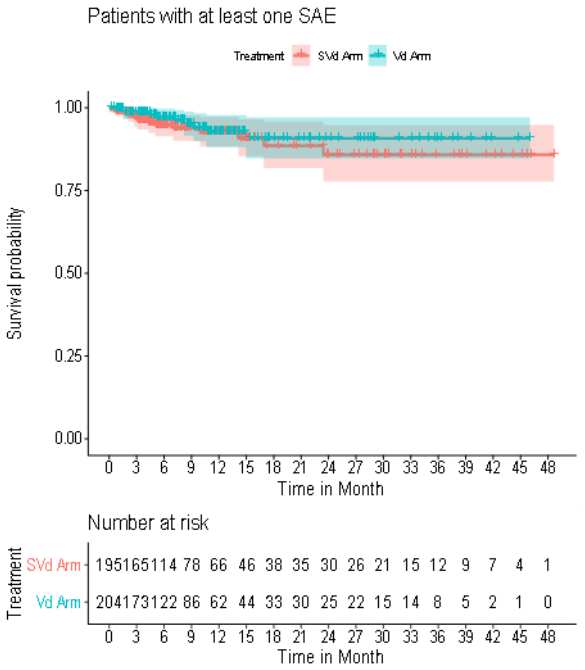

Abbildung 71: Kaplan-Meier-Kurven zu SUE SOC Herzerkrankungen

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

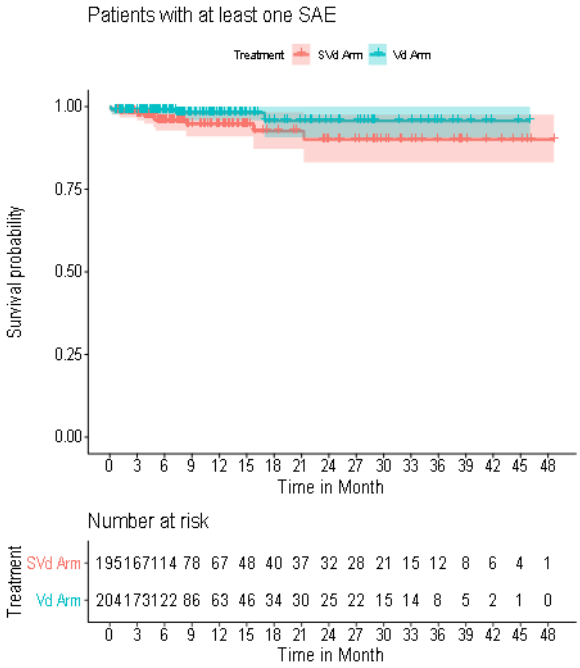

Abbildung 72: Kaplan-Meier-Kurven zu SUE SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

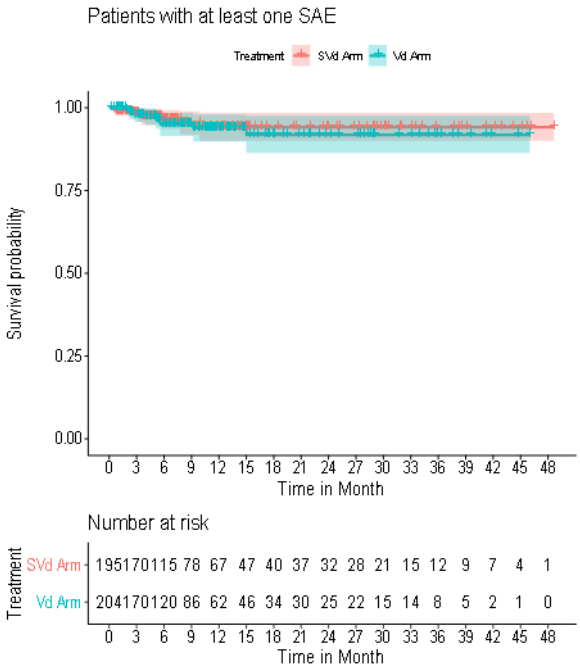

Abbildung 73: Kaplan-Meier-Kurven zu SUE SOC Erkrankungen des Nervensystems

SVd: Selinexor in Kombination mit Bortezomib und Dexamethason; Vd: Bortezomib in Kombination mit Dexamethason

2. Vollständige Darstellung der Subgruppenanalysen zu Modul 4A

2.1 Subgruppenanalysen der Wirksamkeitsendpunkte OS, TTNT, PFS, EORCT-QLQ-CIPN20, EQ-5D-VAS und EORCT-QLQ-C30

Tabelle 1: Vollständige Darstellung der Subgruppenanalysen zu OS und TTNT

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Overall Survival	total	-	SVd Arm	195	68	34,87	127	65,13	36,67	30,19	NA	0,88	0,63	1,22	0,4305	NA
Overall Survival	total	-	Vd Arm	207	80	38,65	127	61,35	32,76	27,83	NA	-	-	-	-	NA
Overall Survival	Gender	Female	SVd Arm	80	30	37,50	50	62,50	31,74	24,97	NA	1,07	0,65	1,77	0,7930	0,3857
Overall Survival	Gender	Female	Vd Arm	92	35	38,04	57	61,96	NA	24,97	NA	-	-	-	-	0,3857
Overall Survival	Gender	Male	SVd Arm	115	38	33,04	77	66,96	36,67	30,19	NA	0,79	0,51	1,24	0,3108	0,3857
Overall Survival	Gender	Male	Vd Arm	115	45	39,13	70	60,87	32,76	25,13	NA	-	-	-	-	0,3857
Overall Survival	Age Group	<65	SVd Arm	86	34	39,53	52	60,47	31,74	24,61	NA	1,85	1,02	3,37	0,0417	0,0019
Overall Survival	Age Group	<65	Vd Arm	75	19	25,33	56	74,67	NA	NA	NA	-	-	-	-	0,0019
Overall Survival	Age Group	>=65	SVd Arm	109	34	31,19	75	68,81	36,67	31,41	NA	0,57	0,37	0,89	0,0113	0,0019
Overall Survival	Age Group	>=65	Vd Arm	132	61	46,21	71	53,79	27,83	21,39	NA	-	-	-	-	0,0019
Overall Survival	Baseline R-ISS stage	Stage I or II	SVd Arm	173	61	35,26	112	64,74	36,67	30,19	NA	0,87	0,61	1,23	0,4256	0,8272
Overall Survival	Baseline R-ISS stage	Stage I or II	Vd Arm	177	68	38,42	109	61,58	32,76	27,83	NA	-	-	-	-	0,8272
Overall Survival	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	12,12	7,98	NA	1,01	0,27	3,76	0,9885	0,8272
Overall Survival	Baseline R-ISS stage	Stage III	Vd Arm	16	10	62,50	6	37,50	16,82	8,94	NA	-	-	-	-	0,8272
Overall Survival	Baseline ISS stage	Stage I or II	SVd Arm	163	52	31,90	111	68,10	36,67	31,74	NA	0,85	0,58	1,23	0,3914	0,3500
Overall Survival	Baseline ISS stage	Stage I or II	Vd Arm	175	60	34,29	115	65,71	NA	29,11	NA	-	-	-	-	0,3500
Overall Survival	Baseline ISS stage	Stage III	SVd Arm	32	16	50,00	16	50,00	12,12	7,98	NA	1,23	0,62	2,45	0,5491	0,3500
Overall Survival	Baseline ISS stage	Stage III	Vd Arm	32	20	62,50	12	37,50	16,82	15,44	NA	-	-	-	-	0,3500
Overall Survival	Region (SAP)	Region 1	SVd Arm	18	6	33,33	12	66,67	36,67	26,68	NA	0,80	0,20	3,27	0,7556	0,2721
Overall Survival	Region (SAP)	Region 1	Vd Arm	18	6	33,33	12	66,67	NA	12,16	NA	-	-	-	-	0,2721
Overall Survival	Region (SAP)	Region 2	SVd Arm	61	22	36,07	39	63,93	NA	24,61	NA	0,75	0,42	1,34	0,3297	0,2721
Overall Survival	Region (SAP)	Region 2	Vd Arm	66	28	42,42	38	57,58	29,11	24,84	NA	-	-	-	-	0,2721
Overall Survival	Region (SAP)	Region 3	SVd Arm	47	14	29,79	33	70,21	NA	31,41	NA	0,65	0,33	1,28	0,2090	0,2721
Overall Survival	Region (SAP)	Region 3	Vd Arm	53	22	41,51	31	58,49	25,13	19,06	NA	-	-	-	-	0,2721
Overall Survival	Region (SAP)	Region 4	SVd Arm	69	26	37,68	43	62,32	30,19	24,97	NA	1,46	0,81	2,61	0,2043	0,2721
Overall Survival	Region (SAP)	Region 4	Vd Arm	70	24	34,29	46	65,71	32,76	27,93	NA	-	-	-	-	0,2721
Overall Survival	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	39	33,33	78	66,67	36,67	31,41	NA	0,64	0,42	0,97	0,0330	0,0094
Overall Survival	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	138	60	43,48	78	56,52	29,01	22,41	NA	-	-	-	-	0,0094
Overall Survival	Region (by medical care situation)	Rest of the world	SVd Arm	78	29	37,18	49	62,82	32,16	24,97	NA	1,67	0,92	3,02	0,0880	0,0094
Overall Survival	Region (by medical care situation)	Rest of the world	Vd Arm	69	20	28,99	49	71,01	NA	NA	NA	-	-	-	-	0,0094
Overall Survival	Race	Races other than White	SVd Arm	34	14	41,18	20	58,82	24,61	15,77	NA	3,26	1,22	8,66	0,0136	0,0040
Overall Survival	Race	Races other than White	Vd Arm	42	8	19,05	34	80,95	NA	NA	NA	-	-	-	-	0,0040
Overall Survival	Race	White	SVd Arm	161	54	33,54	107	66,46	36,67	31,41	NA	0,70	0,49	1,01	0,0572	0,0040
Overall Survival	Race	White	Vd Arm	165	72	43,64	93	56,36	28,62	23,36	NA	-	-	-	-	0,0040
Overall Survival	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	24,97	16,43	NA	2,27	0,19	26,54	0,5019	0,4522
Overall Survival	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	NA	29,11	NA	-	-	-	-	0,4522
Overall Survival	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	59	34,50	112	65,50	32,16	30,19	NA	0,88	0,62	1,25	0,4650	0,4522

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Overall Survival	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	188	73	38,83	115	61,17	32,76	26,91	NA	-	-	-	-	0,4522
Overall Survival	Prior PI therapies	N	SVd Arm	48	10	20,83	38	79,17	NA	NA	NA	0,55	0,25	1,22	0,1356	0,2046
Overall Survival	Prior PI therapies	N	Vd Arm	47	17	36,17	30	63,83	NA	26,58	NA	-	-	-	-	0,2046
Overall Survival	Prior PI therapies	Y	SVd Arm	147	58	39,46	89	60,54	31,74	26,45	NA	0,97	0,68	1,39	0,8686	0,2046
Overall Survival	Prior PI therapies	Y	Vd Arm	160	63	39,38	97	60,62	32,76	24,84	NA	-	-	-	-	0,2046
Overall Survival	Prior anti-MM regimen	>1	SVd Arm	98	35	35,71	63	64,29	31,74	28,39	NA	0,87	0,55	1,39	0,5687	0,9895
Overall Survival	Prior anti-MM regimen	>1	Vd Arm	106	41	38,68	65	61,32	NA	24,84	NA	-	-	-	-	0,9895
Overall Survival	Prior anti-MM regimen	1	SVd Arm	97	33	34,02	64	65,98	NA	26,68	NA	0,88	0,55	1,40	0,5858	0,9895
Overall Survival	Prior anti-MM regimen	1	Vd Arm	101	39	38,61	62	61,39	32,76	25,13	NA	-	-	-	-	0,9895
Overall Survival	Baseline single cytogenetic alterations	N	SVd Arm	98	28	28,57	70	71,43	NA	31,74	NA	0,90	0,55	1,50	0,6979	0,8876
Overall Survival	Baseline single cytogenetic alterations	N	Vd Arm	112	37	33,04	75	66,96	NA	NA	NA	-	-	-	-	0,8876
Overall Survival	Baseline single cytogenetic alterations	Y	SVd Arm	97	40	41,24	57	58,76	28,35	22,21	NA	0,86	0,56	1,34	0,5071	0,8876
Overall Survival	Baseline single cytogenetic alterations	Y	Vd Arm	95	43	45,26	52	54,74	24,97	19,61	NA	-	-	-	-	0,8876
Overall Survival	Prior Bortezomib exposure	N	SVd Arm	61	14	22,95	47	77,05	NA	NA	NA	0,58	0,28	1,20	0,1361	0,2366
Overall Survival	Prior Bortezomib exposure	N	Vd Arm	62	21	33,87	41	66,13	NA	28,62	NA	-	-	-	-	0,2366
Overall Survival	Prior Bortezomib exposure	Y	SVd Arm	134	54	40,30	80	59,70	31,74	26,45	NA	0,95	0,65	1,38	0,7918	0,2366
Overall Survival	Prior Bortezomib exposure	Y	Vd Arm	145	59	40,69	86	59,31	32,76	22,41	NA	-	-	-	-	0,2366
Time to Next Treatment	total	-	SVd Arm	195	114	58,46	81	41,54	15,97	13,63	21,95	0,74	0,57	0,94	0,0144	NA
Time to Next Treatment	total	-	Vd Arm	207	151	72,95	56	27,05	10,84	9,82	13,40	-	-	-	-	NA
Time to Next Treatment	Gender	Female	SVd Arm	80	47	58,75	33	41,25	17,05	14,03	27,43	0,77	0,52	1,16	0,2146	0,9523
Time to Next Treatment	Gender	Female	Vd Arm	92	66	71,74	26	28,26	11,73	9,82	15,87	-	-	-	-	0,9523
Time to Next Treatment	Gender	Male	SVd Arm	115	67	58,26	48	41,74	14,03	10,45	22,60	0,76	0,55	1,05	0,0997	0,9523
Time to Next Treatment	Gender	Male	Vd Arm	115	85	73,91	30	26,09	10,48	8,61	13,73	-	-	-	-	0,9523
Time to Next Treatment	Age Group	<65	SVd Arm	86	53	61,63	33	38,37	14,78	8,61	19,71	0,87	0,59	1,30	0,5063	0,3061
Time to Next Treatment	Age Group	<65	Vd Arm	75	53	70,67	22	29,33	10,38	8,80	14,52	-	-	-	-	0,3061
Time to Next Treatment	Age Group	>=65	SVd Arm	109	61	55,96	48	44,04	18,23	13,93	28,85	0,67	0,48	0,93	0,0152	0,3061
Time to Next Treatment	Age Group	>=65	Vd Arm	132	98	74,24	34	25,76	11,73	9,36	14,55	-	-	-	-	0,3061
Time to Next Treatment	Baseline R-ISS stage	Stage I or II	SVd Arm	173	100	57,80	73	42,20	16,92	14,03	23,43	0,67	0,51	0,87	0,0024	0,4583
Time to Next Treatment	Baseline R-ISS stage	Stage I or II	Vd Arm	177	131	74,01	46	25,99	10,74	9,23	13,14	-	-	-	-	0,4583
Time to Next Treatment	Baseline R-ISS stage	Stage III	SVd Arm	12	6	50,00	6	50,00	8,41	4,53	NA	1,05	0,33	3,39	0,9340	0,4583
Time to Next Treatment	Baseline R-ISS stage	Stage III	Vd Arm	16	10	62,50	6	37,50	10,18	5,36	NA	-	-	-	-	0,4583
Time to Next Treatment	Baseline ISS stage	Stage I or II	SVd Arm	163	96	58,90	67	41,10	17,05	14,06	23,43	0,70	0,54	0,92	0,0090	0,4378
Time to Next Treatment	Baseline ISS stage	Stage I or II	Vd Arm	175	126	72,00	49	28,00	10,97	9,92	13,67	-	-	-	-	0,4378
Time to Next Treatment	Baseline ISS stage	Stage III	SVd Arm	32	18	56,25	14	43,75	8,54	6,70	NA	0,92	0,49	1,71	0,7854	0,4378
Time to Next Treatment	Baseline ISS stage	Stage III	Vd Arm	32	25	78,12	7	21,88	10,18	7,16	21,16	-	-	-	-	0,4378
Time to Next Treatment	Region (SAP)	Region 1	SVd Arm	18	11	61,11	7	38,89	24,54	4,53	NA	0,44	0,16	1,21	0,1009	0,5418
Time to Next Treatment	Region (SAP)	Region 1	Vd Arm	18	13	72,22	5	27,78	7,98	5,91	NA	-	-	-	-	0,5418
Time to Next Treatment	Region (SAP)	Region 2	SVd Arm	61	36	59,02	25	40,98	10,64	7,13	22,87	0,72	0,46	1,12	0,1411	0,5418
Time to Next Treatment	Region (SAP)	Region 2	Vd Arm	66	50	75,76	16	24,24	12,02	6,87	15,34	-	-	-	-	0,5418
Time to Next Treatment	Region (SAP)	Region 3	SVd Arm	47	29	61,70	18	38,30	14,13	13,01	29,83	0,63	0,38	1,06	0,0806	0,5418
Time to Next Treatment	Region (SAP)	Region 3	Vd Arm	53	40	75,47	13	24,53	10,61	8,61	17,08	-	-	-	-	0,5418
Time to Next Treatment	Region (SAP)	Region 4	SVd Arm	69	38	55,07	31	44,93	16,92	14,03	28,85	0,90	0,58	1,41	0,6504	0,5418
Time to Next Treatment	Region (SAP)	Region 4	Vd Arm	70	48	68,57	22	31,43	12,09	10,18	17,12	-	-	-	-	0,5418
Time to Next Treatment	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	69	58,97	48	41,03	16,92	13,01	24,54	0,61	0,45	0,84	0,0020	0,0525

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Time to Next Treatment	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	138	106	76,81	32	23,19	9,95	7,98	13,04	-	-	-	-	0,0525
Time to Next Treatment	Region (by medical care situation)	Rest of the world	SVd Arm	78	45	57,69	33	42,31	15,34	10,64	24,97	1,04	0,68	1,60	0,8590	0,0525
Time to Next Treatment	Region (by medical care situation)	Rest of the world	Vd Arm	69	45	65,22	24	34,78	13,63	10,81	19,65	-	-	-	-	0,0525
Time to Next Treatment	Race	Races other than White	SVd Arm	34	20	58,82	14	41,18	15,34	6,24	NA	1,87	0,96	3,62	0,0606	0,0030
Time to Next Treatment	Race	Races other than White	Vd Arm	42	25	59,52	17	40,48	15,34	10,97	NA	-	-	-	-	0,0030
Time to Next Treatment	Race	White	SVd Arm	161	94	58,39	67	41,61	16,43	13,93	23,29	0,63	0,48	0,83	0,0010	0,0030
Time to Next Treatment	Race	White	Vd Arm	165	126	76,36	39	23,64	10,38	8,57	13,14	-	-	-	-	0,0030
Time to Next Treatment	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	24,97	7,95	NA	0,25	0,03	2,43	0,1966	0,3391
Time to Next Treatment	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	5	100,00	0	0,00	7,98	4,90	NA	-	-	-	-	0,3391
Time to Next Treatment	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	102	59,65	69	40,35	14,78	13,37	21,95	0,76	0,59	0,99	0,0389	0,3391
Time to Next Treatment	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	188	137	72,87	51	27,13	10,84	9,82	13,63	-	-	-	-	0,3391
Time to Next Treatment	Prior PI therapies	N	SVd Arm	48	17	35,42	31	64,58	30,23	26,68	NA	0,42	0,23	0,76	0,0035	0,0407
Time to Next Treatment	Prior PI therapies	N	Vd Arm	47	33	70,21	14	29,79	12,88	10,15	24,67	-	-	-	-	0,0407
Time to Next Treatment	Prior PI therapies	Y	SVd Arm	147	97	65,99	50	34,01	13,93	9,92	16,92	0,83	0,63	1,09	0,1834	0,0407
Time to Next Treatment	Prior PI therapies	Y	Vd Arm	160	118	73,75	42	26,25	10,81	8,71	13,14	-	-	-	-	0,0407
Time to Next Treatment	Prior anti-MM regimen	>1	SVd Arm	98	61	62,24	37	37,76	14,03	11,50	19,12	0,76	0,54	1,07	0,1109	0,7817
Time to Next Treatment	Prior anti-MM regimen	>1	Vd Arm	106	80	75,47	26	24,53	10,18	8,05	13,14	-	-	-	-	0,7817
Time to Next Treatment	Prior anti-MM regimen	1	SVd Arm	97	53	54,64	44	45,36	19,02	15,34	29,83	0,71	0,49	1,02	0,0606	0,7817
Time to Next Treatment	Prior anti-MM regimen	1	Vd Arm	101	71	70,30	30	29,70	13,04	9,92	16,23	-	-	-	-	0,7817
Time to Next Treatment	Baseline single cytogenetic alterations	N	SVd Arm	98	53	54,08	45	45,92	19,02	13,63	30,29	0,76	0,53	1,09	0,1384	0,5162
Time to Next Treatment	Baseline single cytogenetic alterations	N	Vd Arm	112	79	70,54	33	29,46	13,14	10,48	16,23	-	-	-	-	0,5162
Time to Next Treatment	Baseline single cytogenetic alterations	Y	SVd Arm	97	61	62,89	36	37,11	14,13	9,99	18,99	0,65	0,45	0,93	0,0167	0,5162
Time to Next Treatment	Baseline single cytogenetic alterations	Y	Vd Arm	95	72	75,79	23	24,21	8,71	7,16	12,45	-	-	-	-	0,5162
Time to Next Treatment	Prior Bortezomib exposure	N	SVd Arm	61	25	40,98	36	59,02	29,83	22,87	NA	0,47	0,28	0,81	0,0054	0,0720
Time to Next Treatment	Prior Bortezomib exposure	N	Vd Arm	62	41	66,13	21	33,87	12,88	10,38	21,16	-	-	-	-	0,0720
Time to Next Treatment	Prior Bortezomib exposure	Y	SVd Arm	134	89	66,42	45	33,58	13,37	8,61	16,13	0,83	0,62	1,10	0,1890	0,0720
Time to Next Treatment	Prior Bortezomib exposure	Y	Vd Arm	145	110	75,86	35	24,14	10,81	8,57	13,14	-	-	-	-	0,0720

Tabelle 2: Vollständige Darstellung der Subgruppenanalyse zum OS, ergänzende Analyse zum Datenschnitt 22.03.2022

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit	Oberes 95 %-KI der medianen Zeit	HR	Unteres 95 %-KI	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Overall Survival	total	-	SVd Arm	195	74	37,95	121	62,05	36,67	31,74	NA	0,93	0,67	1,27	0,6333	NA
Overall Survival	total	-	Vd Arm	207	83	40,10	124	59,90	NA	26,91	NA	-	-	-	-	NA
Overall Survival	Gender	Female	SVd Arm	80	32	40,00	48	60,00	34,63	24,97	NA	1,08	0,66	1,76	0,7678	0,4887
Overall Survival	Gender	Female	Vd Arm	92	37	40,22	55	59,78	NA	24,97	NA	-	-	-	-	0,4887
Overall Survival	Gender	Male	SVd Arm	115	42	36,52	73	63,48	36,67	31,41	NA	0,85	0,56	1,31	0,4749	0,4887
Overall Survival	Gender	Male	Vd Arm	115	46	40,00	69	60,00	NA	25,13	NA	-	-	-	-	0,4887
Overall Survival	Age Group	<65	SVd Arm	86	38	44,19	48	55,81	34,17	24,61	NA	1,85	1,05	3,27	0,0313	0,0027
Overall Survival	Age Group	<65	Vd Arm	75	21	28,00	54	72,00	NA	NA	NA	-	-	-	-	0,0027
Overall Survival	Age Group	>=65	SVd Arm	109	36	33,03	73	66,97	NA	32,16	NA	0,63	0,41	0,95	0,0281	0,0027
Overall Survival	Age Group	>=65	Vd Arm	132	62	46,97	70	53,03	26,58	21,39	NA	-	-	-	-	0,0027
Overall Survival	Baseline R-ISS stage	Stage I or II	SVd Arm	173	66	38,15	107	61,85	36,67	31,41	NA	0,92	0,66	1,29	0,6247	0,8922
Overall Survival	Baseline R-ISS stage	Stage I or II	Vd Arm	177	71	40,11	106	59,89	NA	26,91	NA	-	-	-	-	0,8922
Overall Survival	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	12,12	7,98	NA	1,01	0,27	3,76	0,9885	0,8922
Overall Survival	Baseline R-ISS stage	Stage III	Vd Arm	16	10	62,50	6	37,50	16,82	8,94	NA	-	-	-	-	0,8922
Overall Survival	Baseline ISS stage	Stage I or II	SVd Arm	163	58	35,58	105	64,42	41,17	34,17	NA	0,92	0,64	1,32	0,6505	0,5285
Overall Survival	Baseline ISS stage	Stage I or II	Vd Arm	175	63	36,00	112	64,00	NA	29,11	NA	-	-	-	-	0,5285
Overall Survival	Baseline ISS stage	Stage III	SVd Arm	32	16	50,00	16	50,00	12,12	7,98	NA	1,18	0,60	2,32	0,6353	0,5285
Overall Survival	Baseline ISS stage	Stage III	Vd Arm	32	20	62,50	12	37,50	16,82	15,44	32,76	-	-	-	-	0,5285
Overall Survival	Region (SAP)	Region 1	SVd Arm	18	6	33,33	12	66,67	NA	26,68	NA	0,80	0,22	2,88	0,7360	0,3508
Overall Survival	Region (SAP)	Region 1	Vd Arm	18	7	38,89	11	61,11	36,80	12,16	NA	-	-	-	-	0,3508
Overall Survival	Region (SAP)	Region 2	SVd Arm	61	26	42,62	35	57,38	34,76	24,61	NA	0,87	0,50	1,51	0,6231	0,3508
Overall Survival	Region (SAP)	Region 2	Vd Arm	66	28	42,42	38	57,58	NA	24,84	NA	-	-	-	-	0,3508
Overall Survival	Region (SAP)	Region 3	SVd Arm	47	14	29,79	33	70,21	NA	31,41	NA	0,65	0,33	1,28	0,2092	0,3508
Overall Survival	Region (SAP)	Region 3	Vd Arm	53	22	41,51	31	58,49	NA	19,06	NA	-	-	-	-	0,3508
Overall Survival	Region (SAP)	Region 4	SVd Arm	69	28	40,58	41	59,42	31,74	24,97	NA	1,41	0,81	2,46	0,2276	0,3508
Overall Survival	Region (SAP)	Region 4	Vd Arm	70	26	37,14	44	62,86	NA	27,93	NA	-	-	-	-	0,3508
Overall Survival	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	42	35,90	75	64,10	41,17	31,74	NA	0,69	0,46	1,03	0,0680	0,0101
Overall Survival	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	138	61	44,20	77	55,80	29,11	23,36	NA	-	-	-	-	0,0101
Overall Survival	Region (by medical care situation)	Rest of the world	SVd Arm	78	32	41,03	46	58,97	32,16	24,97	NA	1,72	0,97	3,03	0,0592	0,0101
Overall Survival	Region (by medical care situation)	Rest of the world	Vd Arm	69	22	31,88	47	68,12	NA	27,96	NA	-	-	-	-	0,0101
Overall Survival	Race	Races other than White	SVd Arm	34	14	41,18	20	58,82	24,61	15,77	NA	3,26	1,22	8,66	0,0136	0,0063
Overall Survival	Race	Races other than White	Vd Arm	42	8	19,05	34	80,95	NA	NA	NA	-	-	-	-	0,0063
Overall Survival	Race	White	SVd Arm	161	60	37,27	101	62,73	36,67	31,74	NA	0,77	0,54	1,08	0,1316	0,0063
Overall Survival	Race	White	Vd Arm	165	75	45,45	90	54,55	28,62	23,36	NA	-	-	-	-	0,0063
Overall Survival	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	24,97	16,43	NA	2,27	0,19	26,54	0,5019	0,4735
Overall Survival	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	NA	29,11	NA	-	-	-	-	0,4735
Overall Survival	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	64	37,43	107	62,57	36,67	31,74	NA	0,92	0,65	1,29	0,6209	0,4735
Overall Survival	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	188	76	40,43	112	59,57	NA	26,91	NA	-	-	-	-	0,4735
Overall Survival	Prior PI therapies	N	SVd Arm	48	11	22,92	37	77,08	NA	NA	NA	0,55	0,26	1,17	0,1167	0,1347
Overall Survival	Prior PI therapies	N	Vd Arm	47	18	38,30	29	61,70	NA	26,91	NA	-	-	-	-	0,1347
Overall Survival	Prior PI therapies	Y	SVd Arm	147	63	42,86	84	57,14	32,16	26,45	NA	1,04	0,73	1,48	0,8268	0,1347

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit	Oberes 95 %-KI der medianen Zeit	HR	Unteres 95 %-KI	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Overall Survival	Prior PI therapies	Y	Vd Arm	160	65	40,62	95	59,38	36,80	24,84	NA	-	-	-	-	0,1347
Overall Survival	Prior anti-MM regimen	>1	SVd Arm	98	36	36,73	62	63,27	36,67	30,19	NA	0,88	0,56	1,39	0,5857	0,7670
Overall Survival	Prior anti-MM regimen	>1	Vd Arm	106	42	39,62	64	60,38	NA	24,84	NA	-	-	-	-	0,7670
Overall Survival	Prior anti-MM regimen	1	SVd Arm	97	38	39,18	59	60,82	36,63	26,68	NA	0,97	0,62	1,51	0,8940	0,7670
Overall Survival	Prior anti-MM regimen	1	Vd Arm	101	41	40,59	60	59,41	36,80	25,13	NA	-	-	-	-	0,7670
Overall Survival	Baseline single cytogenetic alterations	N	SVd Arm	98	32	32,65	66	67,35	NA	34,17	NA	1,00	0,62	1,63	0,9860	0,6707
Overall Survival	Baseline single cytogenetic alterations	N	Vd Arm	112	38	33,93	74	66,07	NA	NA	NA	-	-	-	-	0,6707
Overall Survival	Baseline single cytogenetic alterations	Y	SVd Arm	97	42	43,30	55	56,70	28,35	22,21	NA	0,87	0,57	1,34	0,5347	0,6707
Overall Survival	Baseline single cytogenetic alterations	Y	Vd Arm	95	45	47,37	50	52,63	25,13	19,61	NA	-	-	-	-	0,6707
Overall Survival	Prior Bortezomib exposure	N	SVd Arm	61	15	24,59	46	75,41	NA	NA	NA	0,57	0,28	1,14	0,1054	0,1443
Overall Survival	Prior Bortezomib exposure	N	Vd Arm	62	22	35,48	40	64,52	NA	27,93	NA	-	-	-	-	0,1443
Overall Survival	Prior Bortezomib exposure	Y	SVd Arm	134	59	44,03	75	55,97	32,16	26,45	NA	1,02	0,71	1,46	0,9257	0,1443
Overall Survival	Prior Bortezomib exposure	Y	Vd Arm	145	61	42,07	84	57,93	32,76	22,41	NA	-	-	-	-	0,1443

Tabelle 3: Vollständige Darstellung der Subgruppenanalysen zum PFS

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Progression Free Survival	total	-	SVd Arm	195	92	47,18	103	52,82	13,24	11,73	23,43	0,71	0,54	0,93	0,0124	NA
Progression Free Survival	total	-	Vd Arm	207	137	66,18	70	33,82	9,46	8,11	10,78	-	-	-	-	NA
Progression Free Survival	Gender	Female	SVd Arm	80	33	41,25	47	58,75	18,04	12,91	NA	0,65	0,41	1,04	0,0683	0,6499
Progression Free Survival	Gender	Female	Vd Arm	92	58	63,04	34	36,96	9,66	7,62	14,13	-	-	-	-	0,6499
Progression Free Survival	Gender	Male	SVd Arm	115	59	51,30	56	48,70	12,85	7,95	21,03	0,74	0,53	1,05	0,0915	0,6499
Progression Free Survival	Gender	Male	Vd Arm	115	79	68,70	36	31,30	8,44	7,06	11,89	-	-	-	-	0,6499
Progression Free Survival	Age Group	<65	SVd Arm	86	51	59,30	35	40,70	12,22	6,97	16,62	0,92	0,61	1,38	0,6957	0,1014
Progression Free Survival	Age Group	<65	Vd Arm	75	52	69,33	23	30,67	9,43	6,51	13,60	-	-	-	-	0,1014
Progression Free Survival	Age Group	>=65	SVd Arm	109	41	37,61	68	62,39	18,04	12,91	27,50	0,58	0,39	0,85	0,0048	0,1014
Progression Free Survival	Age Group	>=65	Vd Arm	132	85	64,39	47	35,61	9,46	7,62	12,55	-	-	-	-	0,1014
Progression Free Survival	Baseline R-ISS stage	Stage I or II	SVd Arm	173	78	45,09	95	54,91	15,38	12,91	26,18	0,62	0,47	0,83	0,0012	0,1793
Progression Free Survival	Baseline R-ISS stage	Stage I or II	Vd Arm	177	119	67,23	58	32,77	9,43	7,23	10,71	-	-	-	-	0,1793
Progression Free Survival	Baseline R-ISS stage	Stage III	SVd Arm	12	8	66,67	4	33,33	5,62	3,61	NA	1,35	0,45	4,00	0,5896	0,1793
Progression Free Survival	Baseline R-ISS stage	Stage III	Vd Arm	16	12	75,00	4	25,00	7,62	2,79	NA	-	-	-	-	0,1793
Progression Free Survival	Baseline ISS stage	Stage I or II	SVd Arm	163	74	45,40	89	54,60	15,47	12,91	26,18	0,66	0,49	0,88	0,0052	0,2882
Progression Free Survival	Baseline ISS stage	Stage I or II	Vd Arm	175	112	64,00	63	36,00	9,49	8,34	12,29	-	-	-	-	0,2882
Progression Free Survival	Baseline ISS stage	Stage III	SVd Arm	32	18	56,25	14	43,75	6,97	4,90	NA	0,96	0,51	1,80	0,8987	0,2882
Progression Free Survival	Baseline ISS stage	Stage III	Vd Arm	32	25	78,12	7	21,88	7,26	5,09	17,51	-	-	-	-	0,2882
Progression Free Survival	Region (SAP)	Region 1	SVd Arm	18	5	27,78	13	72,22	NA	3,68	NA	0,47	0,16	1,40	0,1675	0,2247
Progression Free Survival	Region (SAP)	Region 1	Vd Arm	18	12	66,67	6	33,33	8,34	4,24	NA	-	-	-	-	0,2247
Progression Free Survival	Region (SAP)	Region 2	SVd Arm	61	23	37,70	38	62,30	12,91	6,70	NA	0,68	0,39	1,18	0,1665	0,2247
Progression Free Survival	Region (SAP)	Region 2	Vd Arm	66	35	53,03	31	46,97	9,69	6,74	22,93	-	-	-	-	0,2247
Progression Free Survival	Region (SAP)	Region 3	SVd Arm	47	22	46,81	25	53,19	15,47	12,91	29,47	0,54	0,30	0,95	0,0316	0,2247
Progression Free Survival	Region (SAP)	Region 3	Vd Arm	53	37	69,81	16	30,19	8,61	6,90	15,28	-	-	-	-	0,2247
Progression Free Survival	Region (SAP)	Region 4	SVd Arm	69	42	60,87	27	39,13	10,28	7,00	18,04	1,04	0,68	1,58	0,8667	0,2247
Progression Free Survival	Region (SAP)	Region 4	Vd Arm	70	53	75,71	17	24,29	9,46	6,97	15,24	-	-	-	-	0,2247
Progression Free Survival	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	48	41,03	69	58,97	15,47	12,91	29,11	0,54	0,38	0,77	0,0007	0,0124
Progression Free Survival	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	138	92	66,67	46	33,33	8,61	6,83	10,71	-	-	-	-	0,0124
Progression Free Survival	Region (by medical care situation)	Rest of the world	SVd Arm	78	44	56,41	34	43,59	11,73	6,97	23,43	1,12	0,72	1,74	0,6219	0,0124
Progression Free Survival	Region (by medical care situation)	Rest of the world	Vd Arm	69	45	65,22	24	34,78	9,69	8,44	16,49	-	-	-	-	0,0124
Progression Free Survival	Race	Races other than White	SVd Arm	34	19	55,88	15	44,12	10,28	5,75	NA	1,85	0,91	3,78	0,0858	0,0052
Progression Free Survival	Race	Races other than White	Vd Arm	42	23	54,76	19	45,24	10,78	8,44	NA	-	-	-	-	0,0052
Progression Free Survival	Race	White	SVd Arm	161	73	45,34	88	54,66	15,21	12,22	26,74	0,61	0,45	0,83	0,0015	0,0052
Progression Free Survival	Race	White	Vd Arm	165	114	69,09	51	30,91	8,54	6,97	10,71	-	-	-	-	0,0052
Progression Free Survival	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	6,11	4,21	NA	1,00	0,13	7,51	1,0000	0,7782
Progression Free Survival	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	5	100,00	0	0,00	6,74	3,45	NA	-	-	-	-	0,7782
Progression Free Survival	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	85	49,71	86	50,29	13,14	10,18	21,03	0,75	0,56	0,99	0,0411	0,7782

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Progression Free Survival	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	188	127	67,55	61	32,45	9,43	8,11	10,87	-	-	-	-	0,7782
Progression Free Survival	Prior PI therapies	N	SVd Arm	48	10	20,83	38	79,17	29,47	27,50	NA	0,29	0,14	0,62	0,0007	0,0109
Progression Free Survival	Prior PI therapies	N	Vd Arm	47	27	57,45	20	42,55	9,69	8,44	23,69	-	-	-	-	0,0109
Progression Free Survival	Prior PI therapies	Y	SVd Arm	147	82	55,78	65	44,22	11,73	7,62	13,93	0,83	0,62	1,11	0,1985	0,0109
Progression Free Survival	Prior PI therapies	Y	Vd Arm	160	110	68,75	50	31,25	9,43	7,06	10,71	-	-	-	-	0,0109
Progression Free Survival	Prior anti-MM regimen	>1	SVd Arm	98	54	55,10	44	44,90	11,76	7,39	15,38	0,79	0,56	1,14	0,2074	0,3530
Progression Free Survival	Prior anti-MM regimen	>1	Vd Arm	106	73	68,87	33	31,13	8,87	6,24	9,69	-	-	-	-	0,3530
Progression Free Survival	Prior anti-MM regimen	1	SVd Arm	97	38	39,18	59	60,82	23,43	13,24	NA	0,61	0,41	0,93	0,0189	0,3530
Progression Free Survival	Prior anti-MM regimen	1	Vd Arm	101	64	63,37	37	36,63	10,71	8,31	16,39	-	-	-	-	0,3530
Progression Free Survival	Baseline single cytogenetic alterations	N	SVd Arm	98	40	40,82	58	59,18	16,62	11,76	NA	0,73	0,49	1,10	0,1335	0,6801
Progression Free Survival	Baseline single cytogenetic alterations	N	Vd Arm	112	70	62,50	42	37,50	9,66	8,44	15,11	-	-	-	-	0,6801
Progression Free Survival	Baseline single cytogenetic alterations	Y	SVd Arm	97	52	53,61	45	46,39	12,91	7,95	23,43	0,65	0,45	0,95	0,0254	0,6801
Progression Free Survival	Baseline single cytogenetic alterations	Y	Vd Arm	95	67	70,53	28	29,47	8,15	5,75	11,89	-	-	-	-	0,6801
Progression Free Survival	Prior Bortezomib exposure	N	SVd Arm	61	15	24,59	46	75,41	29,47	24,77	NA	0,35	0,18	0,68	0,0014	0,0137
Progression Free Survival	Prior Bortezomib exposure	N	Vd Arm	62	34	54,84	28	45,16	9,69	8,44	17,51	-	-	-	-	0,0137
Progression Free Survival	Prior Bortezomib exposure	Y	SVd Arm	134	77	57,46	57	42,54	10,18	7,39	13,14	0,88	0,65	1,19	0,3970	0,0137
Progression Free Survival	Prior Bortezomib exposure	Y	Vd Arm	145	103	71,03	42	28,97	8,87	6,97	10,68	-	-	-	-	0,0137

Tabelle 4: Vollständige Darstellung der Subgruppenanalysen zu den Fragebögen EORCT-QLQ-CIPN20, EQ-5D-VAS und EORCT-QLQ-C30

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-CIPN20 Sensory Subscale Score	total	-	SVd Arm	191	65	34,03	126	65,97	23,43	11,27	NA	0,65	0,47	0,90	0,0092	NA
EORTC QLQ-CIPN20 Sensory Subscale Score	total	-	Vd Arm	197	88	44,67	109	55,33	19,06	7,82	29,01	-	-	-	-	NA
EORTC QLQ-CIPN20 Sensory Subscale Score	Gender	Female	SVd Arm	78	33	42,31	45	57,69	10,38	6,01	NA	0,76	0,47	1,24	0,2729	0,3798
EORTC QLQ-CIPN20 Sensory Subscale Score	Gender	Female	Vd Arm	86	39	45,35	47	54,65	19,12	5,75	NA	-	-	-	-	0,3798
EORTC QLQ-CIPN20 Sensory Subscale Score	Gender	Male	SVd Arm	113	32	28,32	81	71,68	NA	12,68	NA	0,57	0,36	0,89	0,0127	0,3798
EORTC QLQ-CIPN20 Sensory Subscale Score	Gender	Male	Vd Arm	111	49	44,14	62	55,86	19,06	5,78	NA	-	-	-	-	0,3798
EORTC QLQ-CIPN20 Sensory Subscale Score	Age Group	<65	SVd Arm	84	28	33,33	56	66,67	NA	12,68	NA	0,79	0,45	1,37	0,3983	0,3823
EORTC QLQ-CIPN20 Sensory Subscale Score	Age Group	<65	Vd Arm	74	25	33,78	49	66,22	NA	7,85	NA	-	-	-	-	0,3823
EORTC QLQ-CIPN20 Sensory Subscale Score	Age Group	>=65	SVd Arm	107	37	34,58	70	65,42	12,68	8,51	NA	0,58	0,38	0,87	0,0082	0,3823
EORTC QLQ-CIPN20 Sensory Subscale Score	Age Group	>=65	Vd Arm	123	63	51,22	60	48,78	8,61	4,17	21,29	-	-	-	-	0,3823
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline R-ISS stage	Stage I or II	SVd Arm	170	59	34,71	111	65,29	23,43	11,27	NA	0,65	0,46	0,91	0,0126	0,3935
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline R-ISS stage	Stage I or II	Vd Arm	168	75	44,64	93	55,36	19,12	6,74	NA	-	-	-	-	0,3935
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline R-ISS stage	Stage III	SVd Arm	12	4	33,33	8	66,67	NA	5,75	NA	1,27	0,28	5,70	0,7557	0,3935
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline R-ISS stage	Stage III	Vd Arm	15	6	40,00	9	60,00	NA	3,48	NA	-	-	-	-	0,3935
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline ISS stage	Stage I or II	SVd Arm	159	52	32,70	107	67,30	NA	11,53	NA	0,62	0,43	0,88	0,0076	0,1463
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline ISS stage	Stage I or II	Vd Arm	167	74	44,31	93	55,69	19,12	6,74	NA	-	-	-	-	0,1463
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline ISS stage	Stage III	SVd Arm	32	13	40,62	19	59,38	8,51	5,75	NA	1,18	0,53	2,64	0,6790	0,1463
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline ISS stage	Stage III	Vd Arm	30	14	46,67	16	53,33	19,06	3,48	NA	-	-	-	-	0,1463
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (SAP)	Region 1	SVd Arm	17	2	11,76	15	88,24	NA	NA	NA	0,17	0,02	1,59	0,0867	0,6900
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (SAP)	Region 1	Vd Arm	16	6	37,50	10	62,50	NA	3,06	NA	-	-	-	-	0,6900
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (SAP)	Region 2	SVd Arm	59	18	30,51	41	69,49	NA	11,27	NA	0,70	0,37	1,30	0,2563	0,6900
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (SAP)	Region 2	Vd Arm	59	23	38,98	36	61,02	14,06	4,44	NA	-	-	-	-	0,6900
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (SAP)	Region 3	SVd Arm	46	23	50,00	23	50,00	9,46	6,01	NA	0,67	0,37	1,23	0,1966	0,6900
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (SAP)	Region 3	Vd Arm	52	28	53,85	24	46,15	7,82	3,94	19,35	-	-	-	-	0,6900
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (SAP)	Region 4	SVd Arm	69	22	31,88	47	68,12	23,43	11,53	NA	0,61	0,35	1,06	0,0742	0,6900
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (SAP)	Region 4	Vd Arm	70	31	44,29	39	55,71	20,53	6,74	NA	-	-	-	-	0,6900
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	113	43	38,05	70	61,95	12,68	7,39	NA	0,73	0,49	1,09	0,1191	0,2334
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	59	45,74	70	54,26	8,61	5,75	NA	-	-	-	-	0,2334
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	22	28,21	56	71,79	NA	20,73	NA	0,48	0,27	0,84	0,0089	0,2334
EORTC QLQ-CIPN20 Sensory Subscale Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	29	42,65	39	57,35	20,53	6,74	NA	-	-	-	-	0,2334
EORTC QLQ-CIPN20 Sensory Subscale Score	Race	Races other than White	SVd Arm	34	13	38,24	21	61,76	7,00	4,67	NA	0,94	0,42	2,11	0,8877	0,2892
EORTC QLQ-CIPN20 Sensory Subscale Score	Race	Races other than White	Vd Arm	39	16	41,03	23	58,97	19,12	5,32	NA	-	-	-	-	0,2892
EORTC QLQ-CIPN20 Sensory Subscale Score	Race	White	SVd Arm	157	52	33,12	105	66,88	23,43	11,53	NA	0,59	0,41	0,84	0,0036	0,2892
EORTC QLQ-CIPN20 Sensory Subscale Score	Race	White	Vd Arm	158	72	45,57	86	54,43	19,06	6,67	29,01	-	-	-	-	0,2892
EORTC QLQ-CIPN20 Sensory Subscale Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	2	40,00	3	60,00	5,22	3,48	NA	0,82	0,05	13,24	0,8864	0,8519
EORTC QLQ-CIPN20 Sensory Subscale Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	NA	2,79	NA	-	-	-	-	0,8519
EORTC QLQ-CIPN20 Sensory Subscale Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	168	55	32,74	113	67,26	23,43	11,27	NA	0,62	0,44	0,88	0,0076	0,8519
EORTC QLQ-CIPN20 Sensory Subscale Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	80	44,44	100	55,56	19,06	7,85	NA	-	-	-	-	0,8519

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior PI therapies	N	SVd Arm	46	16	34,78	30	65,22	20,73	9,46	NA	0,59	0,31	1,14	0,1135	0,7480
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior PI therapies	N	Vd Arm	46	23	50,00	23	50,00	7,82	3,48	NA	-	-	-	-	0,7480
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior PI therapies	Y	SVd Arm	145	49	33,79	96	66,21	23,43	11,27	NA	0,67	0,46	0,98	0,0361	0,7480
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior PI therapies	Y	Vd Arm	151	65	43,05	86	56,95	19,12	7,85	NA	-	-	-	-	0,7480
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior anti-MM regimen	>1	SVd Arm	97	31	31,96	66	68,04	NA	10,38	NA	0,52	0,33	0,81	0,0037	0,1436
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior anti-MM regimen	>1	Vd Arm	100	50	50,00	50	50,00	7,85	4,27	NA	-	-	-	-	0,1436
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior anti-MM regimen	1	SVd Arm	94	34	36,17	60	63,83	20,73	10,38	NA	0,84	0,53	1,35	0,4750	0,1436
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior anti-MM regimen	1	Vd Arm	97	38	39,18	59	60,82	19,35	14,06	NA	-	-	-	-	0,1436
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline single cytogenetic alterations	N	SVd Arm	95	32	33,68	63	66,32	20,73	10,38	NA	0,61	0,39	0,95	0,0288	0,6927
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline single cytogenetic alterations	N	Vd Arm	107	52	48,60	55	51,40	19,06	4,14	NA	-	-	-	-	0,6927
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	33	34,38	63	65,62	23,43	9,46	NA	0,70	0,43	1,13	0,1380	0,6927
EORTC QLQ-CIPN20 Sensory Subscale Score	Baseline single cytogenetic alterations	Y	Vd Arm	90	36	40,00	54	60,00	19,15	7,82	NA	-	-	-	-	0,6927
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior Bortezomib exposure	N	SVd Arm	59	22	37,29	37	62,71	20,73	7,39	NA	0,53	0,30	0,93	0,0243	0,3882
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior Bortezomib exposure	N	Vd Arm	60	33	55,00	27	45,00	3,48	3,06	NA	-	-	-	-	0,3882
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior Bortezomib exposure	Y	SVd Arm	132	43	32,58	89	67,42	23,43	11,27	NA	0,72	0,48	1,07	0,1034	0,3882
EORTC QLQ-CIPN20 Sensory Subscale Score	Prior Bortezomib exposure	Y	Vd Arm	137	55	40,15	82	59,85	19,15	14,06	NA	-	-	-	-	0,3882
EORTC QLQ-CIPN20 Motor Subscale Score	total	-	SVd Arm	191	71	37,17	120	62,83	19,58	9,23	NA	0,83	0,60	1,14	0,2433	NA
EORTC QLQ-CIPN20 Motor Subscale Score	total	-	Vd Arm	197	80	40,61	117	59,39	21,29	8,61	NA	-	-	-	-	NA
EORTC QLQ-CIPN20 Motor Subscale Score	Gender	Female	SVd Arm	78	37	47,44	41	52,56	9,13	5,82	26,84	1,03	0,63	1,68	0,9195	0,1767
EORTC QLQ-CIPN20 Motor Subscale Score	Gender	Female	Vd Arm	86	33	38,37	53	61,63	NA	7,85	NA	-	-	-	-	0,1767
EORTC QLQ-CIPN20 Motor Subscale Score	Gender	Male	SVd Arm	113	34	30,09	79	69,91	25,79	11,53	NA	0,65	0,42	1,01	0,0547	0,1767
EORTC QLQ-CIPN20 Motor Subscale Score	Gender	Male	Vd Arm	111	47	42,34	64	57,66	16,23	6,74	NA	-	-	-	-	0,1767
EORTC QLQ-CIPN20 Motor Subscale Score	Age Group	<65	SVd Arm	84	31	36,90	53	63,10	21,88	9,23	NA	1,00	0,58	1,72	0,9886	0,3764
EORTC QLQ-CIPN20 Motor Subscale Score	Age Group	<65	Vd Arm	74	24	32,43	50	67,57	NA	7,85	NA	-	-	-	-	0,3764
EORTC QLQ-CIPN20 Motor Subscale Score	Age Group	>=65	SVd Arm	107	40	37,38	67	62,62	11,53	8,08	NA	0,73	0,49	1,10	0,1338	0,3764
EORTC QLQ-CIPN20 Motor Subscale Score	Age Group	>=65	Vd Arm	123	56	45,53	67	54,47	16,23	4,96	NA	-	-	-	-	0,3764
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline R-ISS stage	Stage I or II	SVd Arm	170	65	38,24	105	61,76	19,58	9,23	NA	0,82	0,58	1,16	0,2607	0,1807
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline R-ISS stage	Stage I or II	Vd Arm	168	68	40,48	100	59,52	21,29	8,61	NA	-	-	-	-	0,1807
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	4,73	4,70	NA	0,24	0,04	1,41	0,0980	0,1807
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline R-ISS stage	Stage III	Vd Arm	15	5	33,33	10	66,67	NA	4,21	NA	-	-	-	-	0,1807
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline ISS stage	Stage I or II	SVd Arm	159	55	34,59	104	65,41	20,04	12,68	NA	0,77	0,54	1,11	0,1589	0,3963
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline ISS stage	Stage I or II	Vd Arm	167	66	39,52	101	60,48	27,89	7,85	NA	-	-	-	-	0,3963
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline ISS stage	Stage III	SVd Arm	32	16	50,00	16	50,00	4,73	4,67	NA	1,11	0,52	2,37	0,7847	0,3963
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline ISS stage	Stage III	Vd Arm	30	14	46,67	16	53,33	16,23	2,37	NA	-	-	-	-	0,3963
EORTC QLQ-CIPN20 Motor Subscale Score	Region (SAP)	Region 1	SVd Arm	17	4	23,53	13	76,47	25,79	6,34	NA	0,39	0,07	2,25	0,2773	0,2693
EORTC QLQ-CIPN20 Motor Subscale Score	Region (SAP)	Region 1	Vd Arm	16	4	25,00	12	75,00	NA	7,85	NA	-	-	-	-	0,2693
EORTC QLQ-CIPN20 Motor Subscale Score	Region (SAP)	Region 2	SVd Arm	59	14	23,73	45	76,27	24,15	11,53	NA	0,54	0,27	1,07	0,0749	0,2693
EORTC QLQ-CIPN20 Motor Subscale Score	Region (SAP)	Region 2	Vd Arm	59	23	38,98	36	61,02	9,00	5,32	NA	-	-	-	-	0,2693
EORTC QLQ-CIPN20 Motor Subscale Score	Region (SAP)	Region 3	SVd Arm	46	23	50,00	23	50,00	9,46	6,01	NA	0,72	0,40	1,30	0,2727	0,2693
EORTC QLQ-CIPN20 Motor Subscale Score	Region (SAP)	Region 3	Vd Arm	52	26	50,00	26	50,00	8,61	3,71	NA	-	-	-	-	0,2693
EORTC QLQ-CIPN20 Motor Subscale Score	Region (SAP)	Region 4	SVd Arm	69	30	43,48	39	56,52	19,58	5,82	NA	1,16	0,68	1,98	0,5777	0,2693

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-CIPN20 Motor Subscale Score	Region (SAP)	Region 4	Vd Arm	70	27	38,57	43	61,43	NA	11,50	NA	-	-	-	-	0,2693
EORTC QLQ-CIPN20 Motor Subscale Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	113	41	36,28	72	63,72	16,16	9,20	NA	0,68	0,45	1,03	0,0646	0,1424
EORTC QLQ-CIPN20 Motor Subscale Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	56	43,41	73	56,59	11,50	5,32	NA	-	-	-	-	0,1424
EORTC QLQ-CIPN20 Motor Subscale Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	30	38,46	48	61,54	20,04	9,13	NA	1,14	0,66	1,97	0,6461	0,1424
EORTC QLQ-CIPN20 Motor Subscale Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	24	35,29	44	64,71	NA	21,29	NA	-	-	-	-	0,1424
EORTC QLQ-CIPN20 Motor Subscale Score	Race	Races other than White	SVd Arm	34	13	38,24	21	61,76	6,18	4,70	NA	0,89	0,39	2,01	0,7722	0,6850
EORTC QLQ-CIPN20 Motor Subscale Score	Race	Races other than White	Vd Arm	39	15	38,46	24	61,54	NA	5,32	NA	-	-	-	-	0,6850
EORTC QLQ-CIPN20 Motor Subscale Score	Race	White	SVd Arm	157	58	36,94	99	63,06	19,58	9,46	NA	0,74	0,51	1,05	0,0933	0,6850
EORTC QLQ-CIPN20 Motor Subscale Score	Race	White	Vd Arm	158	65	41,14	93	58,86	21,29	8,61	NA	-	-	-	-	0,6850
EORTC QLQ-CIPN20 Motor Subscale Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	-	-	-	-	-	-	-	NA
EORTC QLQ-CIPN20 Motor Subscale Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	-	-	-	-	-	-	-	NA
EORTC QLQ-CIPN20 Motor Subscale Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	168	61	36,31	107	63,69	19,58	9,46	NA	0,84	0,60	1,19	0,3326	NA
EORTC QLQ-CIPN20 Motor Subscale Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	71	39,44	109	60,56	27,89	9,00	NA	-	-	-	-	NA
EORTC QLQ-CIPN20 Motor Subscale Score	Prior PI therapies	N	SVd Arm	46	18	39,13	28	60,87	9,46	7,39	NA	0,91	0,47	1,77	0,7842	0,7375
EORTC QLQ-CIPN20 Motor Subscale Score	Prior PI therapies	N	Vd Arm	46	18	39,13	28	60,87	NA	4,17	NA	-	-	-	-	0,7375
EORTC QLQ-CIPN20 Motor Subscale Score	Prior PI therapies	Y	SVd Arm	145	53	36,55	92	63,45	20,04	11,53	NA	0,80	0,55	1,16	0,2371	0,7375
EORTC QLQ-CIPN20 Motor Subscale Score	Prior PI therapies	Y	Vd Arm	151	62	41,06	89	58,94	21,29	7,85	NA	-	-	-	-	0,7375
EORTC QLQ-CIPN20 Motor Subscale Score	Prior anti-MM regimen	>1	SVd Arm	97	33	34,02	64	65,98	26,84	9,23	NA	0,67	0,43	1,05	0,0819	0,1955
EORTC QLQ-CIPN20 Motor Subscale Score	Prior anti-MM regimen	>1	Vd Arm	100	45	45,00	55	55,00	11,50	5,32	NA	-	-	-	-	0,1955
EORTC QLQ-CIPN20 Motor Subscale Score	Prior anti-MM regimen	1	SVd Arm	94	38	40,43	56	59,57	16,16	7,39	NA	1,03	0,65	1,63	0,9052	0,1955
EORTC QLQ-CIPN20 Motor Subscale Score	Prior anti-MM regimen	1	Vd Arm	97	35	36,08	62	63,92	28,55	21,29	NA	-	-	-	-	0,1955
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline single cytogenetic alterations	N	SVd Arm	95	39	41,05	56	58,95	11,53	6,93	NA	0,93	0,60	1,44	0,7379	0,4602
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline single cytogenetic alterations	N	Vd Arm	107	46	42,99	61	57,01	21,29	7,85	NA	-	-	-	-	0,4602
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	32	33,33	64	66,67	26,84	9,46	NA	0,72	0,44	1,18	0,1963	0,4602
EORTC QLQ-CIPN20 Motor Subscale Score	Baseline single cytogenetic alterations	Y	Vd Arm	90	34	37,78	56	62,22	NA	6,70	NA	-	-	-	-	0,4602
EORTC QLQ-CIPN20 Motor Subscale Score	Prior Bortezomib exposure	N	SVd Arm	59	24	40,68	35	59,32	9,46	7,39	NA	0,85	0,47	1,52	0,5818	0,9086
EORTC QLQ-CIPN20 Motor Subscale Score	Prior Bortezomib exposure	N	Vd Arm	60	25	41,67	35	58,33	NA	3,94	NA	-	-	-	-	0,9086
EORTC QLQ-CIPN20 Motor Subscale Score	Prior Bortezomib exposure	Y	SVd Arm	132	47	35,61	85	64,39	20,04	11,53	NA	0,81	0,55	1,21	0,3058	0,9086
EORTC QLQ-CIPN20 Motor Subscale Score	Prior Bortezomib exposure	Y	Vd Arm	137	55	40,15	82	59,85	21,29	8,61	NA	-	-	-	-	0,9086
EORTC QLQ-CIPN20 Autonomic Subscale Score	total	-	SVd Arm	190	128	67,37	62	32,63	3,48	2,76	4,47	0,94	0,73	1,21	0,6490	NA
EORTC QLQ-CIPN20 Autonomic Subscale Score	total	-	Vd Arm	196	127	64,80	69	35,20	2,79	2,10	4,14	-	-	-	-	NA
EORTC QLQ-CIPN20 Autonomic Subscale Score	Gender	Female	SVd Arm	78	60	76,92	18	23,08	2,56	2,33	3,48	0,98	0,67	1,43	0,9169	0,6362
EORTC QLQ-CIPN20 Autonomic Subscale Score	Gender	Female	Vd Arm	85	58	68,24	27	31,76	2,10	1,41	4,21	-	-	-	-	0,6362
EORTC QLQ-CIPN20 Autonomic Subscale Score	Gender	Male	SVd Arm	112	68	60,71	44	39,29	4,47	3,48	6,18	0,87	0,61	1,22	0,4106	0,6362

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-CIPN20 Autonomic Subscale Score	Gender	Male	Vd Arm	111	69	62,16	42	37,84	3,48	2,56	5,55	-	-	-	-	0,6362
EORTC QLQ-CIPN20 Autonomic Subscale Score	Age Group	<65	SVd Arm	83	61	73,49	22	26,51	2,60	2,04	4,30	1,49	0,98	2,26	0,0581	0,0027
EORTC QLQ-CIPN20 Autonomic Subscale Score	Age Group	<65	Vd Arm	74	40	54,05	34	45,95	5,55	3,48	NA	-	-	-	-	0,0027
EORTC QLQ-CIPN20 Autonomic Subscale Score	Age Group	>=65	SVd Arm	107	67	62,62	40	37,38	3,71	3,48	5,78	0,66	0,48	0,92	0,0135	0,0027
EORTC QLQ-CIPN20 Autonomic Subscale Score	Age Group	>=65	Vd Arm	122	87	71,31	35	28,69	2,10	1,41	3,48	-	-	-	-	0,0027
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline R-ISS stage	Stage I or II	SVd Arm	170	115	67,65	55	32,35	3,48	2,76	4,63	0,86	0,66	1,12	0,2574	0,1431
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline R-ISS stage	Stage I or II	Vd Arm	167	111	66,47	56	33,53	2,79	2,10	3,94	-	-	-	-	0,1431
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline R-ISS stage	Stage III	SVd Arm	12	9	75,00	3	25,00	2,35	1,18	NA	1,98	0,67	5,83	0,2110	0,1431
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline R-ISS stage	Stage III	Vd Arm	15	8	53,33	7	46,67	18,20	1,41	NA	-	-	-	-	0,1431
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline ISS stage	Stage I or II	SVd Arm	158	106	67,09	52	32,91	3,48	2,60	4,67	0,96	0,73	1,26	0,7680	0,9273
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline ISS stage	Stage I or II	Vd Arm	166	105	63,25	61	36,75	3,19	2,10	4,21	-	-	-	-	0,9273
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline ISS stage	Stage III	SVd Arm	32	22	68,75	10	31,25	3,48	1,22	4,67	0,99	0,53	1,85	0,9764	0,9273
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline ISS stage	Stage III	Vd Arm	30	22	73,33	8	26,67	2,30	1,41	6,70	-	-	-	-	0,9273
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (SAP)	Region 1	SVd Arm	17	10	58,82	7	41,18	5,78	1,28	NA	0,49	0,17	1,38	0,1689	0,0532
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (SAP)	Region 1	Vd Arm	16	12	75,00	4	25,00	2,79	1,08	NA	-	-	-	-	0,0532
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (SAP)	Region 2	SVd Arm	58	39	67,24	19	32,76	3,48	2,30	5,22	1,13	0,71	1,81	0,6010	0,0532
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (SAP)	Region 2	Vd Arm	58	37	63,79	21	36,21	2,10	1,41	11,10	-	-	-	-	0,0532
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (SAP)	Region 3	SVd Arm	46	31	67,39	15	32,61	4,30	2,56	9,23	0,57	0,34	0,95	0,0297	0,0532
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (SAP)	Region 3	Vd Arm	52	36	69,23	16	30,77	2,10	0,82	4,37	-	-	-	-	0,0532
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (SAP)	Region 4	SVd Arm	69	48	69,57	21	30,43	3,48	2,33	4,67	1,27	0,83	1,96	0,2749	0,0532
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (SAP)	Region 4	Vd Arm	70	42	60,00	28	40,00	4,17	2,89	NA	-	-	-	-	0,0532
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	112	74	66,07	38	33,93	3,52	3,48	5,09	0,73	0,53	1,00	0,0527	0,0064
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	128	88	68,75	40	31,25	2,27	1,41	3,48	-	-	-	-	0,0064
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	54	69,23	24	30,77	3,48	2,33	4,67	1,56	1,00	2,42	0,0477	0,0064
EORTC QLQ-CIPN20 Autonomic Subscale Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	39	57,35	29	42,65	4,86	2,89	NA	-	-	-	-	0,0064
EORTC QLQ-CIPN20 Autonomic Subscale Score	Race	Races other than White	SVd Arm	34	20	58,82	14	41,18	3,55	2,33	NA	1,10	0,57	2,11	0,7840	0,5454
EORTC QLQ-CIPN20 Autonomic Subscale Score	Race	Races other than White	Vd Arm	39	20	51,28	19	48,72	5,55	1,74	NA	-	-	-	-	0,5454
EORTC QLQ-CIPN20 Autonomic Subscale Score	Race	White	SVd Arm	156	108	69,23	48	30,77	3,48	2,56	4,47	0,88	0,67	1,16	0,3611	0,5454
EORTC QLQ-CIPN20 Autonomic Subscale Score	Race	White	Vd Arm	157	107	68,15	50	31,85	2,79	2,10	3,71	-	-	-	-	0,5454
EORTC QLQ-CIPN20 Autonomic Subscale Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-CIPN20 Autonomic Subscale Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	-	-	-	-	-	-	-	NA
EORTC QLQ-CIPN20 Autonomic Subscale Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	167	109	65,27	58	34,73	3,48	2,56	4,47	0,93	0,71	1,21	0,5740	NA
EORTC QLQ-CIPN20 Autonomic Subscale Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	179	116	64,80	63	35,20	3,19	2,10	4,17	-	-	-	-	NA
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior PI therapies	N	SVd Arm	46	30	65,22	16	34,78	3,48	2,33	7,59	0,92	0,55	1,53	0,7492	0,9116
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior PI therapies	N	Vd Arm	46	32	69,57	14	30,43	3,48	2,79	7,82	-	-	-	-	0,9116
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior PI therapies	Y	SVd Arm	144	98	68,06	46	31,94	3,48	2,56	4,47	0,95	0,71	1,27	0,7319	0,9116
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior PI therapies	Y	Vd Arm	150	95	63,33	55	36,67	2,30	1,74	4,17	-	-	-	-	0,9116
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior anti-MM regimen	>1	SVd Arm	96	56	58,33	40	41,67	3,71	3,48	5,78	0,72	0,50	1,03	0,0726	0,0422
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior anti-MM regimen	>1	Vd Arm	100	65	65,00	35	35,00	2,27	1,41	4,21	-	-	-	-	0,0422
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior anti-MM regimen	1	SVd Arm	94	72	76,60	22	23,40	3,48	2,33	4,67	1,21	0,85	1,71	0,2847	0,0422
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior anti-MM regimen	1	Vd Arm	96	62	64,58	34	35,42	3,48	2,14	5,55	-	-	-	-	0,0422
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline single cytogenetic alterations	N	SVd Arm	94	62	65,96	32	34,04	3,71	2,40	5,78	0,96	0,67	1,37	0,8203	0,5255
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline single cytogenetic alterations	N	Vd Arm	106	68	64,15	38	35,85	3,19	2,10	5,55	-	-	-	-	0,5255
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	66	68,75	30	31,25	3,48	2,56	4,63	0,81	0,56	1,17	0,2694	0,5255
EORTC QLQ-CIPN20 Autonomic Subscale Score	Baseline single cytogenetic alterations	Y	Vd Arm	90	59	65,56	31	34,44	2,27	1,41	4,86	-	-	-	-	0,5255
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior Bortezomib exposure	N	SVd Arm	59	38	64,41	21	35,59	3,48	2,33	5,78	0,81	0,51	1,29	0,3793	0,4981
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior Bortezomib exposure	N	Vd Arm	60	43	71,67	17	28,33	3,19	2,10	5,55	-	-	-	-	0,4981
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior Bortezomib exposure	Y	SVd Arm	131	90	68,70	41	31,30	3,52	2,60	4,63	0,98	0,73	1,33	0,9176	0,4981
EORTC QLQ-CIPN20 Autonomic Subscale Score	Prior Bortezomib exposure	Y	Vd Arm	136	84	61,76	52	38,24	2,79	2,07	4,86	-	-	-	-	0,4981
EQ5D02-EQ VAS Score	total	-	SVd Arm	192	104	54,17	88	45,83	7,00	4,70	11,53	1,08	0,82	1,43	0,5815	NA
EQ5D02-EQ VAS Score	total	-	Vd Arm	197	98	49,75	99	50,25	9,07	4,44	16,23	-	-	-	-	NA
EQ5D02-EQ VAS Score	Gender	Female	SVd Arm	79	45	56,96	34	43,04	6,47	3,71	18,66	1,23	0,78	1,93	0,3758	0,5257
EQ5D02-EQ VAS Score	Gender	Female	Vd Arm	86	39	45,35	47	54,65	12,45	4,21	NA	-	-	-	-	0,5257
EQ5D02-EQ VAS Score	Gender	Male	SVd Arm	113	59	52,21	54	47,79	8,08	3,98	12,68	1,01	0,70	1,47	0,9385	0,5257
EQ5D02-EQ VAS Score	Gender	Male	Vd Arm	111	59	53,15	52	46,85	6,70	4,30	16,23	-	-	-	-	0,5257
EQ5D02-EQ VAS Score	Age Group	<65	SVd Arm	85	44	51,76	41	48,24	8,28	4,30	NA	1,27	0,78	2,07	0,3274	0,4968
EQ5D02-EQ VAS Score	Age Group	<65	Vd Arm	73	30	41,10	43	58,90	12,45	4,70	NA	-	-	-	-	0,4968
EQ5D02-EQ VAS Score	Age Group	>=65	SVd Arm	107	60	56,07	47	43,93	6,93	3,71	12,68	1,03	0,72	1,47	0,8550	0,4968
EQ5D02-EQ VAS Score	Age Group	>=65	Vd Arm	124	68	54,84	56	45,16	6,70	4,17	16,23	-	-	-	-	0,4968
EQ5D02-EQ VAS Score	Baseline R-ISS stage	Stage I or II	SVd Arm	171	94	54,97	77	45,03	7,00	4,70	11,56	1,04	0,78	1,40	0,7708	0,1404
EQ5D02-EQ VAS Score	Baseline R-ISS stage	Stage I or II	Vd Arm	169	85	50,30	84	49,70	8,61	4,30	20,30	-	-	-	-	0,1404
EQ5D02-EQ VAS Score	Baseline R-ISS stage	Stage III	SVd Arm	12	7	58,33	5	41,67	4,70	1,22	NA	2,83	0,78	10,26	0,1029	0,1404
EQ5D02-EQ VAS Score	Baseline R-ISS stage	Stage III	Vd Arm	15	5	33,33	10	66,67	NA	10,15	NA	-	-	-	-	0,1404
EQ5D02-EQ VAS Score	Baseline ISS stage	Stage I or II	SVd Arm	160	85	53,12	75	46,88	7,16	4,30	12,68	1,02	0,76	1,38	0,8770	0,3030
EQ5D02-EQ VAS Score	Baseline ISS stage	Stage I or II	Vd Arm	168	86	51,19	82	48,81	6,70	4,30	15,67	-	-	-	-	0,3030

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EQ5D02-EQ VAS Score	Baseline ISS stage	Stage III	SVd Arm	32	19	59,38	13	40,62	6,93	3,48	NA	1,57	0,74	3,34	0,2381	0,3030
EQ5D02-EQ VAS Score	Baseline ISS stage	Stage III	Vd Arm	29	12	41,38	17	58,62	16,23	5,78	NA	-	-	-	-	0,3030
EQ5D02-EQ VAS Score	Region (SAP)	Region 1	SVd Arm	17	5	29,41	12	70,59	NA	3,81	NA	0,50	0,14	1,82	0,2813	0,5531
EQ5D02-EQ VAS Score	Region (SAP)	Region 1	Vd Arm	17	7	41,18	10	58,82	11,27	9,07	NA	-	-	-	-	0,5531
EQ5D02-EQ VAS Score	Region (SAP)	Region 2	SVd Arm	60	36	60,00	24	40,00	3,71	3,48	9,17	1,31	0,78	2,17	0,3042	0,5531
EQ5D02-EQ VAS Score	Region (SAP)	Region 2	Vd Arm	58	28	48,28	30	51,72	5,88	3,02	NA	-	-	-	-	0,5531
EQ5D02-EQ VAS Score	Region (SAP)	Region 3	SVd Arm	46	30	65,22	16	34,78	6,93	3,48	13,90	0,96	0,57	1,62	0,8780	0,5531
EQ5D02-EQ VAS Score	Region (SAP)	Region 3	Vd Arm	52	33	63,46	19	36,54	4,40	3,22	13,60	-	-	-	-	0,5531
EQ5D02-EQ VAS Score	Region (SAP)	Region 4	SVd Arm	69	33	47,83	36	52,17	12,68	7,00	NA	1,07	0,64	1,78	0,7971	0,5531
EQ5D02-EQ VAS Score	Region (SAP)	Region 4	Vd Arm	70	30	42,86	40	57,14	NA	4,70	NA	-	-	-	-	0,5531
EQ5D02-EQ VAS Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	114	64	56,14	50	43,86	6,93	3,81	11,56	0,97	0,69	1,38	0,8698	0,4048
EQ5D02-EQ VAS Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	70	54,26	59	45,74	6,70	4,21	12,45	-	-	-	-	0,4048
EQ5D02-EQ VAS Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	40	51,28	38	48,72	8,28	4,70	NA	1,26	0,76	2,07	0,3665	0,4048
EQ5D02-EQ VAS Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	28	41,18	40	58,82	NA	4,70	NA	-	-	-	-	0,4048
EQ5D02-EQ VAS Score	Race	Races other than White	SVd Arm	34	16	47,06	18	52,94	7,00	4,63	NA	1,92	0,85	4,34	0,1142	0,1170
EQ5D02-EQ VAS Score	Race	Races other than White	Vd Arm	39	12	30,77	27	69,23	NA	11,27	NA	-	-	-	-	0,1170
EQ5D02-EQ VAS Score	Race	White	SVd Arm	158	88	55,70	70	44,30	6,93	3,81	11,56	0,95	0,70	1,29	0,7619	0,1170
EQ5D02-EQ VAS Score	Race	White	Vd Arm	158	86	54,43	72	45,57	5,65	4,17	13,60	-	-	-	-	0,1170
EQ5D02-EQ VAS Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	3	60,00	2	40,00	-	-	-	-	-	-	-	NA
EQ5D02-EQ VAS Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	-	-	-	-	-	-	-	NA
EQ5D02-EQ VAS Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	169	89	52,66	80	47,34	7,16	4,70	13,86	1,07	0,79	1,44	0,6709	NA
EQ5D02-EQ VAS Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	89	49,44	91	50,56	10,15	4,63	20,30	-	-	-	-	NA
EQ5D02-EQ VAS Score	Prior PI therapies	N	SVd Arm	47	21	44,68	26	55,32	13,86	4,63	NA	1,13	0,60	2,12	0,7140	0,8925
EQ5D02-EQ VAS Score	Prior PI therapies	N	Vd Arm	46	20	43,48	26	56,52	NA	4,70	NA	-	-	-	-	0,8925
EQ5D02-EQ VAS Score	Prior PI therapies	Y	SVd Arm	145	83	57,24	62	42,76	6,24	3,71	10,71	1,07	0,78	1,47	0,6647	0,8925
EQ5D02-EQ VAS Score	Prior PI therapies	Y	Vd Arm	151	78	51,66	73	48,34	6,70	4,21	16,23	-	-	-	-	0,8925
EQ5D02-EQ VAS Score	Prior anti-MM regimen	>1	SVd Arm	97	50	51,55	47	48,45	8,28	3,71	18,66	1,03	0,69	1,55	0,8770	0,7515
EQ5D02-EQ VAS Score	Prior anti-MM regimen	>1	Vd Arm	100	47	47,00	53	53,00	10,32	4,30	NA	-	-	-	-	0,7515
EQ5D02-EQ VAS Score	Prior anti-MM regimen	1	SVd Arm	95	54	56,84	41	43,16	6,47	4,30	11,53	1,13	0,77	1,67	0,5375	0,7515
EQ5D02-EQ VAS Score	Prior anti-MM regimen	1	Vd Arm	97	51	52,58	46	47,42	9,07	4,17	21,78	-	-	-	-	0,7515
EQ5D02-EQ VAS Score	Baseline single cytogenetic alterations	N	SVd Arm	96	52	54,17	44	45,83	6,93	4,63	12,68	1,19	0,80	1,77	0,3852	0,4000
EQ5D02-EQ VAS Score	Baseline single cytogenetic alterations	N	Vd Arm	107	51	47,66	56	52,34	9,07	4,70	NA	-	-	-	-	0,4000
EQ5D02-EQ VAS Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	52	54,17	44	45,83	9,23	3,48	13,93	0,93	0,62	1,40	0,7410	0,4000
EQ5D02-EQ VAS Score	Baseline single cytogenetic alterations	Y	Vd Arm	90	47	52,22	43	47,78	10,15	3,48	20,30	-	-	-	-	0,4000
EQ5D02-EQ VAS Score	Prior Bortezomib exposure	N	SVd Arm	60	28	46,67	32	53,33	13,90	4,63	NA	0,95	0,55	1,62	0,8458	0,4937
EQ5D02-EQ VAS Score	Prior Bortezomib exposure	N	Vd Arm	60	30	50,00	30	50,00	10,15	3,25	NA	-	-	-	-	0,4937
EQ5D02-EQ VAS Score	Prior Bortezomib exposure	Y	SVd Arm	132	76	57,58	56	42,42	6,24	3,71	9,17	1,18	0,85	1,65	0,3225	0,4937

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EQ5D02-EQ VAS Score	Prior Bortezomib exposure	Y	Vd Arm	137	68	49,64	69	50,36	9,07	4,30	20,30	-	-	-	-	0,4937
EORTC QLQ-C30 Symptom Scales Fatigue Score	total	-	SVd Arm	192	119	61,98	73	38,02	4,63	3,48	6,93	1,09	0,84	1,41	0,5341	NA
EORTC QLQ-C30 Symptom Scales Fatigue Score	total	-	Vd Arm	197	111	56,35	86	43,65	4,17	2,89	11,10	-	-	-	-	NA
EORTC QLQ-C30 Symptom Scales Fatigue Score	Gender	Female	SVd Arm	78	48	61,54	30	38,46	5,75	3,71	14,06	1,11	0,71	1,72	0,6491	0,9362
EORTC QLQ-C30 Symptom Scales Fatigue Score	Gender	Female	Vd Arm	86	41	47,67	45	52,33	11,27	2,79	NA	-	-	-	-	0,9362
EORTC QLQ-C30 Symptom Scales Fatigue Score	Gender	Male	SVd Arm	114	71	62,28	43	37,72	3,48	3,48	6,18	1,08	0,77	1,52	0,6467	0,9362
EORTC QLQ-C30 Symptom Scales Fatigue Score	Gender	Male	Vd Arm	111	70	63,06	41	36,94	3,71	2,79	5,78	-	-	-	-	0,9362
EORTC QLQ-C30 Symptom Scales Fatigue Score	Age Group	<65	SVd Arm	85	52	61,18	33	38,82	4,67	3,48	10,32	1,10	0,71	1,70	0,6607	0,8900
EORTC QLQ-C30 Symptom Scales Fatigue Score	Age Group	<65	Vd Arm	74	40	54,05	34	45,95	4,40	2,27	NA	-	-	-	-	0,8900
EORTC QLQ-C30 Symptom Scales Fatigue Score	Age Group	>=65	SVd Arm	107	67	62,62	40	37,38	3,71	2,86	6,93	1,15	0,82	1,61	0,4327	0,8900
EORTC QLQ-C30 Symptom Scales Fatigue Score	Age Group	>=65	Vd Arm	123	71	57,72	52	42,28	4,17	2,83	15,21	-	-	-	-	0,8900
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline R-ISS stage	Stage I or II	SVd Arm	170	107	62,94	63	37,06	4,63	3,48	6,93	0,99	0,76	1,31	0,9708	0,0735
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline R-ISS stage	Stage I or II	Vd Arm	168	99	58,93	69	41,07	4,04	2,79	6,70	-	-	-	-	0,0735
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline R-ISS stage	Stage III	SVd Arm	12	8	66,67	4	33,33	3,68	1,22	NA	3,69	0,90	15,06	0,0572	0,0735
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline R-ISS stage	Stage III	Vd Arm	15	3	20,00	12	80,00	NA	NA	NA	-	-	-	-	0,0735
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline ISS stage	Stage I or II	SVd Arm	160	101	63,12	59	36,88	4,30	3,48	6,93	1,04	0,79	1,38	0,7757	0,5199
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline ISS stage	Stage I or II	Vd Arm	167	98	58,68	69	41,32	4,04	2,79	8,08	-	-	-	-	0,5199
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline ISS stage	Stage III	SVd Arm	32	18	56,25	14	43,75	5,75	3,48	NA	1,35	0,64	2,84	0,4247	0,5199
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline ISS stage	Stage III	Vd Arm	30	13	43,33	17	56,67	21,29	4,50	NA	-	-	-	-	0,5199
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (SAP)	Region 1	SVd Arm	18	11	61,11	7	38,89	3,68	2,33	NA	0,72	0,26	1,98	0,5281	0,0866
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (SAP)	Region 1	Vd Arm	17	11	64,71	6	35,29	3,06	1,38	NA	-	-	-	-	0,0866
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (SAP)	Region 2	SVd Arm	59	41	69,49	18	30,51	3,48	2,30	4,63	1,21	0,75	1,95	0,4284	0,0866
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (SAP)	Region 2	Vd Arm	58	32	55,17	26	44,83	2,76	1,64	NA	-	-	-	-	0,0866
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (SAP)	Region 3	SVd Arm	46	29	63,04	17	36,96	6,01	3,48	16,53	0,61	0,36	1,03	0,0607	0,0866
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (SAP)	Region 3	Vd Arm	52	36	69,23	16	30,77	2,83	2,10	4,50	-	-	-	-	0,0866
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (SAP)	Region 4	SVd Arm	69	38	55,07	31	44,93	6,97	3,48	21,88	1,45	0,88	2,38	0,1437	0,0866
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (SAP)	Region 4	Vd Arm	70	32	45,71	38	54,29	21,29	5,16	NA	-	-	-	-	0,0866
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	114	69	60,53	45	39,47	3,94	3,48	6,93	0,79	0,57	1,10	0,1675	0,0028
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	83	64,34	46	35,66	2,79	2,10	4,17	-	-	-	-	0,0028
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	50	64,10	28	35,90	4,67	2,86	8,08	1,94	1,20	3,16	0,0064	0,0028

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Scales Fatigue Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	28	41,18	40	58,82	21,29	6,70	NA	-	-	-	-	0,0028
EORTC QLQ-C30 Symptom Scales Fatigue Score	Race	Races other than White	SVd Arm	34	23	67,65	11	32,35	3,68	2,60	8,28	1,74	0,92	3,30	0,0844	0,0979
EORTC QLQ-C30 Symptom Scales Fatigue Score	Race	Races other than White	Vd Arm	40	19	47,50	21	52,50	11,27	2,20	NA	-	-	-	-	0,0979
EORTC QLQ-C30 Symptom Scales Fatigue Score	Race	White	SVd Arm	158	96	60,76	62	39,24	4,63	3,48	7,39	0,96	0,72	1,29	0,8023	0,0979
EORTC QLQ-C30 Symptom Scales Fatigue Score	Race	White	Vd Arm	157	92	58,60	65	41,40	4,04	2,79	6,70	-	-	-	-	0,0979
EORTC QLQ-C30 Symptom Scales Fatigue Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	3	60,00	2	40,00	26,45	3,48	NA	1,76	0,16	19,57	0,6419	0,7129
EORTC QLQ-C30 Symptom Scales Fatigue Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	1,45	0,72	NA	-	-	-	-	0,7129
EORTC QLQ-C30 Symptom Scales Fatigue Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	169	103	60,95	66	39,05	4,63	3,48	6,93	1,12	0,84	1,48	0,4463	0,7129
EORTC QLQ-C30 Symptom Scales Fatigue Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	101	56,11	79	43,89	4,50	3,06	11,27	-	-	-	-	0,7129
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior PI therapies	N	SVd Arm	46	30	65,22	16	34,78	3,55	2,37	14,06	1,53	0,89	2,66	0,1243	0,1603
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior PI therapies	N	Vd Arm	46	25	54,35	21	45,65	5,16	3,22	NA	-	-	-	-	0,1603
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior PI therapies	Y	SVd Arm	146	89	60,96	57	39,04	4,63	3,48	6,93	0,98	0,73	1,32	0,8934	0,1603
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior PI therapies	Y	Vd Arm	151	86	56,95	65	43,05	4,07	2,20	11,27	-	-	-	-	0,1603
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior anti-MM regimen	>1	SVd Arm	97	61	62,89	36	37,11	3,71	2,60	7,39	0,97	0,67	1,39	0,8561	0,3570
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior anti-MM regimen	>1	Vd Arm	101	60	59,41	41	40,59	3,06	2,10	8,61	-	-	-	-	0,3570
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior anti-MM regimen	1	SVd Arm	95	58	61,05	37	38,95	4,63	3,52	7,39	1,24	0,84	1,82	0,2728	0,3570
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior anti-MM regimen	1	Vd Arm	96	51	53,12	45	46,88	6,70	3,94	21,78	-	-	-	-	0,3570
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline single cytogenetic alterations	N	SVd Arm	96	60	62,50	36	37,50	4,63	2,86	7,39	1,07	0,75	1,55	0,7042	0,7494
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline single cytogenetic alterations	N	Vd Arm	106	61	57,55	45	42,45	4,17	2,89	21,29	-	-	-	-	0,7494
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	59	61,46	37	38,54	3,71	3,48	10,32	0,98	0,67	1,45	0,9360	0,7494
EORTC QLQ-C30 Symptom Scales Fatigue Score	Baseline single cytogenetic alterations	Y	Vd Arm	91	50	54,95	41	45,05	4,40	2,33	13,60	-	-	-	-	0,7494
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior Bortezomib exposure	N	SVd Arm	59	37	62,71	22	37,29	3,48	2,37	11,50	1,24	0,77	2,01	0,3682	0,5427
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior Bortezomib exposure	N	Vd Arm	60	36	60,00	24	40,00	4,17	2,79	NA	-	-	-	-	0,5427
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior Bortezomib exposure	Y	SVd Arm	133	82	61,65	51	38,35	4,67	3,48	7,16	1,04	0,76	1,43	0,8021	0,5427
EORTC QLQ-C30 Symptom Scales Fatigue Score	Prior Bortezomib exposure	Y	Vd Arm	137	75	54,74	62	45,26	4,50	2,76	15,21	-	-	-	-	0,5427
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	total	-	SVd Arm	192	135	70,31	57	29,69	2,33	1,41	3,94	2,00	1,52	2,63	0,0000	NA
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	total	-	Vd Arm	197	90	45,69	107	54,31	9,03	5,09	NA	-	-	-	-	NA
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Gender	Female	SVd Arm	78	57	73,08	21	26,92	2,56	1,64	4,63	2,17	1,38	3,40	0,0006	0,5654
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Gender	Female	Vd Arm	86	37	43,02	49	56,98	11,27	4,14	NA	-	-	-	-	0,5654

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Gender	Male	SVd Arm	114	78	68,42	36	31,58	1,64	1,22	4,63	1,83	1,28	2,62	0,0008	0,5654
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Gender	Male	Vd Arm	111	53	47,75	58	52,25	7,85	4,86	NA	-	-	-	-	0,5654
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Age Group	<65	SVd Arm	85	67	78,82	18	21,18	1,25	1,18	2,33	3,12	1,94	5,01	0,0000	0,0107
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Age Group	<65	Vd Arm	74	26	35,14	48	64,86	NA	7,85	NA	-	-	-	-	0,0107
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Age Group	>=65	SVd Arm	107	68	63,55	39	36,45	4,63	2,33	5,22	1,45	1,02	2,06	0,0397	0,0107
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Age Group	>=65	Vd Arm	123	64	52,03	59	47,97	5,52	4,14	23,36	-	-	-	-	0,0107
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline R-ISS stage	Stage I or II	SVd Arm	170	118	69,41	52	30,59	2,33	1,64	4,63	1,77	1,33	2,36	0,0001	0,2057
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline R-ISS stage	Stage I or II	Vd Arm	168	81	48,21	87	51,79	7,85	4,86	NA	-	-	-	-	0,2057
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline R-ISS stage	Stage III	SVd Arm	12	10	83,33	2	16,67	1,18	1,18	NA	3,87	1,19	12,58	0,0192	0,2057
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline R-ISS stage	Stage III	Vd Arm	15	6	40,00	9	60,00	NA	3,48	NA	-	-	-	-	0,2057
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline ISS stage	Stage I or II	SVd Arm	160	110	68,75	50	31,25	2,33	1,41	4,63	1,97	1,46	2,65	0,0000	0,5654
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline ISS stage	Stage I or II	Vd Arm	167	76	45,51	91	54,49	8,61	5,09	NA	-	-	-	-	0,5654
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline ISS stage	Stage III	SVd Arm	32	25	78,12	7	21,88	2,33	1,18	6,93	2,46	1,22	4,97	0,0094	0,5654
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline ISS stage	Stage III	Vd Arm	30	14	46,67	16	53,33	17,05	4,50	NA	-	-	-	-	0,5654
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (SAP)	Region 1	SVd Arm	18	13	72,22	5	27,78	1,41	1,18	NA	1,55	0,60	4,05	0,3623	0,1225
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (SAP)	Region 1	Vd Arm	17	10	58,82	7	41,18	7,85	1,41	NA	-	-	-	-	0,1225
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (SAP)	Region 2	SVd Arm	59	37	62,71	22	37,29	2,40	1,18	6,87	2,51	1,42	4,44	0,0011	0,1225
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (SAP)	Region 2	Vd Arm	58	19	32,76	39	67,24	NA	7,20	NA	-	-	-	-	0,1225
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (SAP)	Region 3	SVd Arm	46	31	67,39	15	32,61	3,94	2,33	4,83	1,20	0,70	2,06	0,5028	0,1225
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (SAP)	Region 3	Vd Arm	52	29	55,77	23	44,23	4,50	3,25	NA	-	-	-	-	0,1225
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (SAP)	Region 4	SVd Arm	69	54	78,26	15	21,74	1,38	1,22	4,63	2,68	1,67	4,29	0,0000	0,1225
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (SAP)	Region 4	Vd Arm	70	32	45,71	38	54,29	17,05	5,09	NA	-	-	-	-	0,1225
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	114	76	66,67	38	33,33	3,94	2,33	4,67	1,74	1,23	2,47	0,0017	0,2165
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	59	45,74	70	54,26	7,85	4,63	NA	-	-	-	-	0,2165
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (by medical care situation)	Rest of the world	SVd Arm	78	59	75,64	19	24,36	1,25	1,18	2,60	2,52	1,58	4,03	0,0001	0,2165
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Region (by medical care situation)	Rest of the world	Vd Arm	68	31	45,59	37	54,41	17,05	4,17	NA	-	-	-	-	0,2165
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Race	Races other than White	SVd Arm	34	25	73,53	9	26,47	2,12	1,22	6,87	2,53	1,30	4,93	0,0050	0,4633
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Race	Races other than White	Vd Arm	40	17	42,50	23	57,50	11,27	2,17	NA	-	-	-	-	0,4633
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Race	White	SVd Arm	158	110	69,62	48	30,38	2,33	1,38	4,63	1,92	1,41	2,61	0,0000	0,4633
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Race	White	Vd Arm	157	73	46,50	84	53,50	7,85	5,09	NA	-	-	-	-	0,4633

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	5,22	1,18	NA	3,35	0,34	33,36	0,2769	0,6649
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	NA	1,45	NA	-	-	-	-	0,6649
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	169	121	71,60	48	28,40	2,33	1,25	3,58	2,01	1,51	2,67	0,0000	0,6649
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	84	46,67	96	53,33	8,61	5,09	NA	-	-	-	-	0,6649
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior PI therapies	N	SVd Arm	46	31	67,39	15	32,61	3,48	2,33	5,82	2,55	1,42	4,61	0,0013	0,3592
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior PI therapies	N	Vd Arm	46	19	41,30	27	58,70	NA	4,86	NA	-	-	-	-	0,3592
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior PI therapies	Y	SVd Arm	146	104	71,23	42	28,77	1,64	1,22	4,63	1,87	1,38	2,54	0,0000	0,3592
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior PI therapies	Y	Vd Arm	151	71	47,02	80	52,98	8,61	4,50	NA	-	-	-	-	0,3592
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior anti-MM regimen	>1	SVd Arm	97	70	72,16	27	27,84	1,64	1,22	3,48	1,86	1,28	2,71	0,0010	0,5817
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior anti-MM regimen	>1	Vd Arm	101	50	49,50	51	50,50	5,09	2,79	NA	-	-	-	-	0,5817
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior anti-MM regimen	1	SVd Arm	95	65	68,42	30	31,58	3,58	1,64	4,83	2,17	1,46	3,24	0,0001	0,5817
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior anti-MM regimen	1	Vd Arm	96	40	41,67	56	58,33	23,36	7,85	NA	-	-	-	-	0,5817
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline single cytogenetic alterations	N	SVd Arm	96	66	68,75	30	31,25	2,33	1,22	4,67	1,83	1,27	2,64	0,0011	0,5372
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline single cytogenetic alterations	N	Vd Arm	106	54	50,94	52	49,06	7,20	4,14	NA	-	-	-	-	0,5372
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline single cytogenetic alterations	Y	SVd Arm	96	69	71,88	27	28,12	2,33	1,38	4,63	2,18	1,43	3,34	0,0002	0,5372
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Baseline single cytogenetic alterations	Y	Vd Arm	91	36	39,56	55	60,44	23,36	4,86	NA	-	-	-	-	0,5372
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior Bortezomib exposure	N	SVd Arm	59	43	72,88	16	27,12	2,33	1,18	3,94	2,98	1,76	5,03	0,0000	0,0819
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior Bortezomib exposure	N	Vd Arm	60	25	41,67	35	58,33	NA	4,86	NA	-	-	-	-	0,0819
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior Bortezomib exposure	Y	SVd Arm	133	92	69,17	41	30,83	2,33	1,38	4,63	1,72	1,25	2,38	0,0009	0,0819
EORTC QLQ-C30 Symptom Scales Nausea and Vomiting	Prior Bortezomib exposure	Y	Vd Arm	137	65	47,45	72	52,55	8,61	4,63	NA	-	-	-	-	0,0819
EORTC QLQ-C30 Symptom Scales Pain Score	total	-	SVd Arm	192	112	58,33	80	41,67	4,67	3,52	8,11	0,73	0,56	0,94	0,0157	NA
EORTC QLQ-C30 Symptom Scales Pain Score	total	-	Vd Arm	196	128	65,31	68	34,69	2,56	2,10	3,71	-	-	-	-	NA
EORTC QLQ-C30 Symptom Scales Pain Score	Gender	Female	SVd Arm	78	46	58,97	32	41,03	5,68	3,48	9,23	0,75	0,49	1,14	0,1780	0,7631
EORTC QLQ-C30 Symptom Scales Pain Score	Gender	Female	Vd Arm	85	52	61,18	33	38,82	2,79	1,48	10,15	-	-	-	-	0,7631
EORTC QLQ-C30 Symptom Scales Pain Score	Gender	Male	SVd Arm	114	66	57,89	48	42,11	4,63	3,48	10,41	0,69	0,49	0,97	0,0344	0,7631
EORTC QLQ-C30 Symptom Scales Pain Score	Gender	Male	Vd Arm	111	76	68,47	35	31,53	2,27	2,10	4,17	-	-	-	-	0,7631
EORTC QLQ-C30 Symptom Scales Pain Score	Age Group	<65	SVd Arm	85	49	57,65	36	42,35	5,75	2,76	12,98	1,00	0,64	1,55	0,9953	0,1043
EORTC QLQ-C30 Symptom Scales Pain Score	Age Group	<65	Vd Arm	74	40	54,05	34	45,95	3,71	2,10	NA	-	-	-	-	0,1043
EORTC QLQ-C30 Symptom Scales Pain Score	Age Group	>=65	SVd Arm	107	63	58,88	44	41,12	4,67	3,48	7,62	0,63	0,45	0,88	0,0065	0,1043

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Scales Pain Score	Age Group	>=65	Vd Arm	122	88	72,13	34	27,87	2,14	1,41	3,19	-	-	-	-	0,1043
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline R-ISS stage	Stage I or II	SVd Arm	170	100	58,82	70	41,18	5,59	3,71	8,38	0,64	0,49	0,84	0,0011	0,0029
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline R-ISS stage	Stage I or II	Vd Arm	167	116	69,46	51	30,54	2,17	2,04	3,45	-	-	-	-	0,0029
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline R-ISS stage	Stage III	SVd Arm	12	12	100,00	0	0,00	1,77	1,18	NA	4,19	1,25	13,99	0,0143	0,0029
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline R-ISS stage	Stage III	Vd Arm	15	5	33,33	10	66,67	NA	10,15	NA	-	-	-	-	0,0029
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline ISS stage	Stage I or II	SVd Arm	160	87	54,37	73	45,62	5,68	4,30	10,38	0,61	0,46	0,81	0,0006	0,0061
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline ISS stage	Stage I or II	Vd Arm	166	112	67,47	54	32,53	2,14	1,74	3,25	-	-	-	-	0,0061
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline ISS stage	Stage III	SVd Arm	32	25	78,12	7	21,88	2,40	2,33	8,28	1,67	0,86	3,24	0,1242	0,0061
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline ISS stage	Stage III	Vd Arm	30	16	53,33	14	46,67	5,78	2,83	NA	-	-	-	-	0,0061
EORTC QLQ-C30 Symptom Scales Pain Score	Region (SAP)	Region 1	SVd Arm	18	7	38,89	11	61,11	NA	3,48	NA	0,26	0,09	0,77	0,0095	0,0113
EORTC QLQ-C30 Symptom Scales Pain Score	Region (SAP)	Region 1	Vd Arm	17	12	70,59	5	29,41	1,41	1,08	NA	-	-	-	-	0,0113
EORTC QLQ-C30 Symptom Scales Pain Score	Region (SAP)	Region 2	SVd Arm	59	29	49,15	30	50,85	4,67	3,48	NA	0,46	0,28	0,76	0,0016	0,0113
EORTC QLQ-C30 Symptom Scales Pain Score	Region (SAP)	Region 2	Vd Arm	58	43	74,14	15	25,86	1,68	1,41	2,89	-	-	-	-	0,0113
EORTC QLQ-C30 Symptom Scales Pain Score	Region (SAP)	Region 3	SVd Arm	46	30	65,22	16	34,78	6,93	3,94	12,98	0,70	0,41	1,18	0,1737	0,0113
EORTC QLQ-C30 Symptom Scales Pain Score	Region (SAP)	Region 3	Vd Arm	51	32	62,75	19	37,25	2,27	1,61	5,55	-	-	-	-	0,0113
EORTC QLQ-C30 Symptom Scales Pain Score	Region (SAP)	Region 4	SVd Arm	69	46	66,67	23	33,33	3,71	2,40	8,28	1,17	0,75	1,81	0,4902	0,0113
EORTC QLQ-C30 Symptom Scales Pain Score	Region (SAP)	Region 4	Vd Arm	70	41	58,57	29	41,43	4,86	2,37	NA	-	-	-	-	0,0113
EORTC QLQ-C30 Symptom Scales Pain Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	114	60	52,63	54	47,37	6,93	4,60	12,98	0,56	0,40	0,79	0,0008	0,0185
EORTC QLQ-C30 Symptom Scales Pain Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	128	87	67,97	41	32,03	2,10	1,48	3,45	-	-	-	-	0,0185
EORTC QLQ-C30 Symptom Scales Pain Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	52	66,67	26	33,33	3,48	2,37	7,43	1,08	0,71	1,66	0,7147	0,0185
EORTC QLQ-C30 Symptom Scales Pain Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	41	60,29	27	39,71	3,19	2,17	NA	-	-	-	-	0,0185
EORTC QLQ-C30 Symptom Scales Pain Score	Race	Races other than White	SVd Arm	34	23	67,65	11	32,35	3,48	2,37	8,28	0,96	0,53	1,75	0,9002	0,3114
EORTC QLQ-C30 Symptom Scales Pain Score	Race	Races other than White	Vd Arm	40	27	67,50	13	32,50	2,56	2,04	10,12	-	-	-	-	0,3114
EORTC QLQ-C30 Symptom Scales Pain Score	Race	White	SVd Arm	158	89	56,33	69	43,67	6,87	3,94	10,38	0,68	0,51	0,92	0,0107	0,3114
EORTC QLQ-C30 Symptom Scales Pain Score	Race	White	Vd Arm	156	101	64,74	55	35,26	2,79	2,10	4,17	-	-	-	-	0,3114
EORTC QLQ-C30 Symptom Scales Pain Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	-	-	-	-	-	-	-	NA
EORTC QLQ-C30 Symptom Scales Pain Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	-	-	-	-	-	-	-	NA
EORTC QLQ-C30 Symptom Scales Pain Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	169	98	57,99	71	42,01	4,67	3,52	8,38	0,73	0,56	0,97	0,0273	NA
EORTC QLQ-C30 Symptom Scales Pain Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	179	115	64,25	64	35,75	2,79	2,10	4,40	-	-	-	-	NA

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Scales Pain Score	Prior PI therapies	N	SVd Arm	46	28	60,87	18	39,13	3,94	3,48	NA	0,89	0,52	1,53	0,6804	0,3871
EORTC QLQ-C30 Symptom Scales Pain Score	Prior PI therapies	N	Vd Arm	46	30	65,22	16	34,78	3,25	2,10	10,15	-	-	-	-	0,3871
EORTC QLQ-C30 Symptom Scales Pain Score	Prior PI therapies	Y	SVd Arm	146	84	57,53	62	42,47	5,75	3,68	8,28	0,68	0,51	0,92	0,0112	0,3871
EORTC QLQ-C30 Symptom Scales Pain Score	Prior PI therapies	Y	Vd Arm	150	98	65,33	52	34,67	2,17	1,74	3,48	-	-	-	-	0,3871
EORTC QLQ-C30 Symptom Scales Pain Score	Prior anti-MM regimen	>1	SVd Arm	97	62	63,92	35	36,08	3,48	2,37	8,28	0,79	0,55	1,13	0,1900	0,5067
EORTC QLQ-C30 Symptom Scales Pain Score	Prior anti-MM regimen	>1	Vd Arm	100	65	65,00	35	35,00	2,17	1,64	3,71	-	-	-	-	0,5067
EORTC QLQ-C30 Symptom Scales Pain Score	Prior anti-MM regimen	1	SVd Arm	95	50	52,63	45	47,37	6,87	4,63	17,28	0,66	0,45	0,97	0,0327	0,5067
EORTC QLQ-C30 Symptom Scales Pain Score	Prior anti-MM regimen	1	Vd Arm	96	63	65,62	33	34,38	2,79	2,10	5,55	-	-	-	-	0,5067
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline single cytogenetic alterations	N	SVd Arm	96	54	56,25	42	43,75	6,47	4,63	8,51	0,73	0,51	1,07	0,1022	0,7362
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline single cytogenetic alterations	N	Vd Arm	106	67	63,21	39	36,79	3,19	2,14	5,55	-	-	-	-	0,7362
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	58	60,42	38	39,58	3,94	2,76	10,41	0,67	0,46	0,97	0,0347	0,7362
EORTC QLQ-C30 Symptom Scales Pain Score	Baseline single cytogenetic alterations	Y	Vd Arm	90	61	67,78	29	32,22	2,10	1,45	3,25	-	-	-	-	0,7362
EORTC QLQ-C30 Symptom Scales Pain Score	Prior Bortezomib exposure	N	SVd Arm	59	34	57,63	25	42,37	4,47	3,48	17,28	0,71	0,44	1,15	0,1586	0,9761
EORTC QLQ-C30 Symptom Scales Pain Score	Prior Bortezomib exposure	N	Vd Arm	60	41	68,33	19	31,67	2,56	2,10	5,55	-	-	-	-	0,9761
EORTC QLQ-C30 Symptom Scales Pain Score	Prior Bortezomib exposure	Y	SVd Arm	133	78	58,65	55	41,35	5,75	3,68	8,28	0,71	0,52	0,98	0,0338	0,9761
EORTC QLQ-C30 Symptom Scales Pain Score	Prior Bortezomib exposure	Y	Vd Arm	136	87	63,97	49	36,03	2,79	2,07	4,17	-	-	-	-	0,9761
EORTC QLQ-C30 Symptom Items Appetite Loss Score	total	-	SVd Arm	192	141	73,44	51	26,56	2,33	2,33	3,52	1,49	1,16	1,91	0,0018	NA
EORTC QLQ-C30 Symptom Items Appetite Loss Score	total	-	Vd Arm	197	116	58,88	81	41,12	4,17	3,48	5,88	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Gender	Female	SVd Arm	78	63	80,77	15	19,23	2,33	1,38	3,48	2,09	1,40	3,12	0,0002	0,0304
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Gender	Female	Vd Arm	86	45	52,33	41	47,67	4,47	3,25	NA	-	-	-	-	0,0304
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Gender	Male	SVd Arm	114	78	68,42	36	31,58	2,89	2,33	5,78	1,17	0,84	1,64	0,3421	0,0304
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Gender	Male	Vd Arm	111	71	63,96	40	36,04	3,75	3,22	6,70	-	-	-	-	0,0304
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Age Group	<65	SVd Arm	85	67	78,82	18	21,18	2,04	1,25	3,55	2,34	1,52	3,61	0,0001	0,0067
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Age Group	<65	Vd Arm	74	34	45,95	40	54,05	6,70	4,47	NA	-	-	-	-	0,0067
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Age Group	>=65	SVd Arm	107	74	69,16	33	30,84	3,48	2,33	4,67	1,11	0,81	1,54	0,5070	0,0067
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Age Group	>=65	Vd Arm	123	82	66,67	41	33,33	3,48	2,79	4,86	-	-	-	-	0,0067
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline R-ISS stage	Stage I or II	SVd Arm	170	124	72,94	46	27,06	2,37	2,33	4,30	1,33	1,02	1,73	0,0354	0,1472
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline R-ISS stage	Stage I or II	Vd Arm	168	107	63,69	61	36,31	3,75	3,22	5,09	-	-	-	-	0,1472
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline R-ISS stage	Stage III	SVd Arm	12	10	83,33	2	16,67	3,04	1,18	NA	3,33	0,99	11,23	0,0432	0,1472
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline R-ISS stage	Stage III	Vd Arm	15	4	26,67	11	73,33	NA	NA	NA	-	-	-	-	0,1472

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline ISS stage	Stage I or II	SVd Arm	160	115	71,88	45	28,12	2,33	2,33	3,71	1,40	1,07	1,84	0,0135	0,2192
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline ISS stage	Stage I or II	Vd Arm	167	104	62,28	63	37,72	4,07	3,25	5,55	-	-	-	-	0,2192
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline ISS stage	Stage III	SVd Arm	32	26	81,25	6	18,75	2,33	1,22	6,24	2,24	1,12	4,49	0,0198	0,2192
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline ISS stage	Stage III	Vd Arm	30	12	40,00	18	60,00	NA	2,76	NA	-	-	-	-	0,2192
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (SAP)	Region 1	SVd Arm	18	13	72,22	5	27,78	2,40	2,33	NA	1,16	0,44	3,04	0,7650	0,0087
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (SAP)	Region 1	Vd Arm	17	14	82,35	3	17,65	3,45	1,41	NA	-	-	-	-	0,0087
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (SAP)	Region 2	SVd Arm	59	44	74,58	15	25,42	2,10	1,22	4,67	1,67	1,03	2,71	0,0346	0,0087
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (SAP)	Region 2	Vd Arm	58	30	51,72	28	48,28	5,88	3,48	NA	-	-	-	-	0,0087
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (SAP)	Region 3	SVd Arm	46	31	67,39	15	32,61	4,70	3,48	9,23	0,66	0,40	1,10	0,1115	0,0087
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (SAP)	Region 3	Vd Arm	52	38	73,08	14	26,92	3,25	2,10	5,09	-	-	-	-	0,0087
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (SAP)	Region 4	SVd Arm	69	53	76,81	16	23,19	2,33	1,22	3,55	2,05	1,31	3,22	0,0015	0,0087
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (SAP)	Region 4	Vd Arm	70	34	48,57	36	51,43	20,50	3,19	NA	-	-	-	-	0,0087
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	114	80	70,18	34	29,82	3,48	2,33	4,70	1,15	0,83	1,58	0,3939	0,0465
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	82	63,57	47	36,43	4,07	3,25	5,55	-	-	-	-	0,0465
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	61	78,21	17	21,79	2,04	1,22	3,48	2,01	1,29	3,13	0,0018	0,0465
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	34	50,00	34	50,00	7,82	2,89	NA	-	-	-	-	0,0465
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Race	Races other than White	SVd Arm	34	27	79,41	7	20,59	2,56	1,28	7,00	1,45	0,81	2,61	0,2088	0,9429
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Race	Races other than White	Vd Arm	40	25	62,50	15	37,50	4,24	2,89	11,27	-	-	-	-	0,9429
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Race	White	SVd Arm	158	114	72,15	44	27,85	2,33	2,33	3,71	1,49	1,12	1,98	0,0058	0,9429
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Race	White	Vd Arm	157	91	57,96	66	42,04	4,17	3,25	7,03	-	-	-	-	0,9429
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	3	60,00	2	40,00	8,08	3,48	NA	0,25	0,03	2,43	0,1966	0,1117
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	5	100,00	0	0,00	1,41	1,38	NA	-	-	-	-	0,1117
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	169	125	73,96	44	26,04	2,33	2,33	3,52	1,60	1,22	2,09	0,0005	0,1117
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	103	57,22	77	42,78	4,47	3,48	7,03	-	-	-	-	0,1117
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior PI therapies	N	SVd Arm	46	35	76,09	11	23,91	2,33	2,10	4,67	2,43	1,44	4,11	0,0007	0,0365
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior PI therapies	N	Vd Arm	46	25	54,35	21	45,65	7,20	4,14	NA	-	-	-	-	0,0365
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior PI therapies	Y	SVd Arm	146	106	72,60	40	27,40	2,56	2,04	4,24	1,28	0,96	1,71	0,0859	0,0365
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior PI therapies	Y	Vd Arm	151	91	60,26	60	39,74	3,61	2,79	5,09	-	-	-	-	0,0365
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior anti-MM regimen	>1	SVd Arm	97	72	74,23	25	25,77	2,30	1,25	2,60	1,54	1,09	2,19	0,0138	0,7600

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior anti-MM regimen	>1	Vd Arm	101	62	61,39	39	38,61	4,14	3,22	5,59	-	-	-	-	0,7600
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior anti-MM regimen	1	SVd Arm	95	69	72,63	26	27,37	3,48	2,33	5,82	1,43	0,99	2,05	0,0522	0,7600
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior anti-MM regimen	1	Vd Arm	96	54	56,25	42	43,75	4,50	3,25	11,07	-	-	-	-	0,7600
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline single cytogenetic alterations	N	SVd Arm	96	72	75,00	24	25,00	2,37	1,35	4,63	1,55	1,10	2,20	0,0122	0,5401
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline single cytogenetic alterations	N	Vd Arm	106	64	60,38	42	39,62	4,17	3,48	7,20	-	-	-	-	0,5401
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	69	71,88	27	28,12	2,33	2,10	4,24	1,33	0,91	1,93	0,1396	0,5401
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Baseline single cytogenetic alterations	Y	Vd Arm	91	52	57,14	39	42,86	4,14	2,79	11,07	-	-	-	-	0,5401
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior Bortezomib exposure	N	SVd Arm	59	44	74,58	15	25,42	2,33	1,25	4,63	2,16	1,36	3,44	0,0009	0,0985
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior Bortezomib exposure	N	Vd Arm	60	37	61,67	23	38,33	4,86	3,22	20,50	-	-	-	-	0,0985
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior Bortezomib exposure	Y	SVd Arm	133	97	72,93	36	27,07	2,56	2,30	4,60	1,35	1,00	1,83	0,0493	0,0985
EORTC QLQ-C30 Symptom Items Appetite Loss Score	Prior Bortezomib exposure	Y	Vd Arm	137	79	57,66	58	42,34	4,14	3,25	6,70	-	-	-	-	0,0985
EORTC QLQ-C30 Symptom Items Diarrhoea Score	total	-	SVd Arm	190	97	51,05	93	48,95	6,97	5,82	10,61	0,91	0,69	1,22	0,5362	NA
EORTC QLQ-C30 Symptom Items Diarrhoea Score	total	-	Vd Arm	195	97	49,74	98	50,26	6,70	4,24	19,35	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Gender	Female	SVd Arm	78	39	50,00	39	50,00	6,93	5,78	16,13	0,89	0,56	1,42	0,6329	0,7982
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Gender	Female	Vd Arm	84	42	50,00	42	50,00	7,82	3,45	NA	-	-	-	-	0,7982
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Gender	Male	SVd Arm	112	58	51,79	54	48,21	7,00	5,78	11,53	0,97	0,66	1,41	0,8590	0,7982
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Gender	Male	Vd Arm	111	55	49,55	56	50,45	5,78	4,17	NA	-	-	-	-	0,7982
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Age Group	<65	SVd Arm	84	54	64,29	30	35,71	5,82	4,63	8,41	1,69	1,06	2,70	0,0250	0,0007
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Age Group	<65	Vd Arm	74	29	39,19	45	60,81	NA	5,55	NA	-	-	-	-	0,0007
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Age Group	>=65	SVd Arm	106	43	40,57	63	59,43	11,53	6,93	NA	0,59	0,40	0,87	0,0076	0,0007
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Age Group	>=65	Vd Arm	121	68	56,20	53	43,80	4,63	3,45	11,27	-	-	-	-	0,0007
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline R-ISS stage	Stage I or II	SVd Arm	169	89	52,66	80	47,34	6,93	5,82	10,61	0,89	0,66	1,20	0,4364	0,2757
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline R-ISS stage	Stage I or II	Vd Arm	166	84	50,60	82	49,40	6,70	4,17	19,35	-	-	-	-	0,2757
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline R-ISS stage	Stage III	SVd Arm	12	4	33,33	8	66,67	NA	1,18	NA	0,43	0,12	1,52	0,1816	0,2757
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline R-ISS stage	Stage III	Vd Arm	15	8	53,33	7	46,67	4,63	2,37	NA	-	-	-	-	0,2757
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline ISS stage	Stage I or II	SVd Arm	158	82	51,90	76	48,10	6,93	5,78	10,61	0,92	0,68	1,25	0,6006	0,3451
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline ISS stage	Stage I or II	Vd Arm	165	82	49,70	83	50,30	7,20	3,81	20,04	-	-	-	-	0,3451
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline ISS stage	Stage III	SVd Arm	32	15	46,88	17	53,12	9,23	6,93	NA	0,62	0,28	1,34	0,2169	0,3451
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline ISS stage	Stage III	Vd Arm	30	15	50,00	15	50,00	5,55	2,79	NA	-	-	-	-	0,3451
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (SAP)	Region 1	SVd Arm	18	11	61,11	7	38,89	4,73	3,94	NA	0,80	0,29	2,17	0,6583	0,2740

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (SAP)	Region 1	Vd Arm	17	11	64,71	6	35,29	3,48	1,41	NA	-	-	-	-	0,2740
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (SAP)	Region 2	SVd Arm	58	30	51,72	28	48,28	4,63	3,48	NA	1,12	0,66	1,88	0,6752	0,2740
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (SAP)	Region 2	Vd Arm	58	28	48,28	30	51,72	8,67	4,24	NA	-	-	-	-	0,2740
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (SAP)	Region 3	SVd Arm	45	20	44,44	25	55,56	13,93	6,93	NA	0,53	0,28	0,99	0,0431	0,2740
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (SAP)	Region 3	Vd Arm	50	26	52,00	24	48,00	5,55	3,71	NA	-	-	-	-	0,2740
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (SAP)	Region 4	SVd Arm	69	36	52,17	33	47,83	8,51	6,93	16,13	1,05	0,64	1,72	0,8340	0,2740
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (SAP)	Region 4	Vd Arm	70	32	45,71	38	54,29	NA	3,45	NA	-	-	-	-	0,2740
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	112	56	50,00	56	50,00	6,93	5,78	11,79	0,83	0,58	1,20	0,3288	0,4566
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	127	65	51,18	62	48,82	5,78	4,24	13,34	-	-	-	-	0,4566
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	41	52,56	37	47,44	7,03	5,85	11,53	1,05	0,65	1,70	0,8465	0,4566
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	32	47,06	36	52,94	6,70	3,19	NA	-	-	-	-	0,4566
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Race	Races other than White	SVd Arm	34	15	44,12	19	55,88	7,00	3,45	NA	1,00	0,49	2,04	0,9916	0,7460
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Race	Races other than White	Vd Arm	40	18	45,00	22	55,00	11,27	2,79	NA	-	-	-	-	0,7460
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Race	White	SVd Arm	156	82	52,56	74	47,44	6,93	5,82	10,61	0,88	0,64	1,21	0,4438	0,7460
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Race	White	Vd Arm	155	79	50,97	76	49,03	5,78	4,17	19,35	-	-	-	-	0,7460
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	-	-	-	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	-	-	-	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	167	85	50,90	82	49,10	7,00	5,82	11,50	0,94	0,69	1,28	0,7067	NA
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	178	87	48,88	91	51,12	7,20	4,40	20,04	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior PI therapies	N	SVd Arm	46	22	47,83	24	52,17	10,41	4,67	NA	0,94	0,51	1,73	0,8433	0,9168
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior PI therapies	N	Vd Arm	46	22	47,83	24	52,17	7,82	4,90	NA	-	-	-	-	0,9168
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior PI therapies	Y	SVd Arm	144	75	52,08	69	47,92	6,93	5,78	10,61	0,91	0,65	1,25	0,5515	0,9168
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior PI therapies	Y	Vd Arm	149	75	50,34	74	49,66	5,55	3,48	20,04	-	-	-	-	0,9168
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior anti-MM regimen	>1	SVd Arm	96	46	47,92	50	52,08	7,00	5,85	13,93	0,63	0,42	0,93	0,0187	0,0058
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior anti-MM regimen	>1	Vd Arm	100	58	58,00	42	42,00	3,48	2,79	8,61	-	-	-	-	0,0058
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior anti-MM regimen	1	SVd Arm	94	51	54,26	43	45,74	6,93	5,59	11,50	1,42	0,93	2,17	0,1071	0,0058
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior anti-MM regimen	1	Vd Arm	95	39	41,05	56	58,95	19,35	7,20	NA	-	-	-	-	0,0058
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline single cytogenetic alterations	N	SVd Arm	94	52	55,32	42	44,68	6,93	5,78	10,41	0,97	0,66	1,42	0,8627	0,6046
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline single cytogenetic alterations	N	Vd Arm	105	57	54,29	48	45,71	4,96	3,48	20,04	-	-	-	-	0,6046

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	45	46,88	51	53,12	10,41	5,78	16,13	0,83	0,54	1,28	0,3968	0,6046
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Baseline single cytogenetic alterations	Y	Vd Arm	90	40	44,44	50	55,56	8,67	4,40	NA	-	-	-	-	0,6046
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior Bortezomib exposure	N	SVd Arm	58	29	50,00	29	50,00	9,23	5,82	18,46	0,88	0,51	1,53	0,6598	0,8196
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior Bortezomib exposure	N	Vd Arm	60	30	50,00	30	50,00	7,20	3,48	NA	-	-	-	-	0,8196
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior Bortezomib exposure	Y	SVd Arm	132	68	51,52	64	48,48	6,93	5,78	10,61	0,95	0,68	1,34	0,7852	0,8196
EORTC QLQ-C30 Symptom Items Diarrhoea Score	Prior Bortezomib exposure	Y	Vd Arm	135	67	49,63	68	50,37	5,55	3,81	NA	-	-	-	-	0,8196
EORTC QLQ-C30 Symptom Items Dyspnoea Score	total	-	SVd Arm	192	111	57,81	81	42,19	5,09	3,48	8,15	0,80	0,61	1,03	0,0879	NA
EORTC QLQ-C30 Symptom Items Dyspnoea Score	total	-	Vd Arm	197	120	60,91	77	39,09	2,83	2,10	4,86	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Gender	Female	SVd Arm	78	46	58,97	32	41,03	5,59	3,48	12,68	0,68	0,45	1,04	0,0767	0,7127
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Gender	Female	Vd Arm	86	51	59,30	35	40,70	2,79	1,74	11,27	-	-	-	-	0,7127
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Gender	Male	SVd Arm	114	65	57,02	49	42,98	4,30	3,48	8,51	0,76	0,54	1,08	0,1204	0,7127
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Gender	Male	Vd Arm	111	69	62,16	42	37,84	2,83	2,10	6,70	-	-	-	-	0,7127
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Age Group	<65	SVd Arm	85	51	60,00	34	40,00	4,30	2,76	10,38	0,90	0,58	1,39	0,6266	0,4100
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Age Group	<65	Vd Arm	74	39	52,70	35	47,30	4,40	2,10	NA	-	-	-	-	0,4100
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Age Group	>=65	SVd Arm	107	60	56,07	47	43,93	6,01	3,48	8,51	0,71	0,51	1,00	0,0501	0,4100
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Age Group	>=65	Vd Arm	123	81	65,85	42	34,15	2,79	2,10	4,86	-	-	-	-	0,4100
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline R-ISS stage	Stage I or II	SVd Arm	170	101	59,41	69	40,59	4,63	3,48	8,38	0,78	0,59	1,03	0,0745	0,3789
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline R-ISS stage	Stage I or II	Vd Arm	168	105	62,50	63	37,50	2,79	2,10	4,86	-	-	-	-	0,3789
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline R-ISS stage	Stage III	SVd Arm	12	7	58,33	5	41,67	5,75	3,52	NA	1,38	0,40	4,84	0,6094	0,3789
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline R-ISS stage	Stage III	Vd Arm	15	5	33,33	10	66,67	NA	2,10	NA	-	-	-	-	0,3789
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline ISS stage	Stage I or II	SVd Arm	160	91	56,88	69	43,12	4,63	3,48	8,38	0,74	0,56	0,99	0,0406	0,3317
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline ISS stage	Stage I or II	Vd Arm	167	104	62,28	63	37,72	2,79	2,10	4,86	-	-	-	-	0,3317
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline ISS stage	Stage III	SVd Arm	32	20	62,50	12	37,50	6,93	3,48	9,23	1,07	0,54	2,11	0,8421	0,3317
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline ISS stage	Stage III	Vd Arm	30	16	53,33	14	46,67	7,00	2,10	NA	-	-	-	-	0,3317
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (SAP)	Region 1	SVd Arm	18	8	44,44	10	55,56	6,18	4,63	NA	0,43	0,15	1,24	0,1106	0,2146
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (SAP)	Region 1	Vd Arm	17	10	58,82	7	41,18	4,86	1,38	NA	-	-	-	-	0,2146
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (SAP)	Region 2	SVd Arm	59	40	67,80	19	32,20	2,66	2,33	3,71	1,07	0,67	1,70	0,7825	0,2146
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (SAP)	Region 2	Vd Arm	58	35	60,34	23	39,66	2,10	1,41	11,76	-	-	-	-	0,2146
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (SAP)	Region 3	SVd Arm	46	27	58,70	19	41,30	5,59	3,48	NA	0,56	0,33	0,95	0,0288	0,2146
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (SAP)	Region 3	Vd Arm	52	34	65,38	18	34,62	2,10	1,41	4,86	-	-	-	-	0,2146

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (SAP)	Region 4	SVd Arm	69	36	52,17	33	47,83	8,51	3,71	17,74	0,76	0,48	1,22	0,2547	0,2146
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (SAP)	Region 4	Vd Arm	70	41	58,57	29	41,43	4,86	2,14	NA	-	-	-	-	0,2146
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	114	67	58,77	47	41,23	4,30	3,48	8,15	0,75	0,54	1,05	0,0963	0,8757
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	78	60,47	51	39,53	2,83	1,74	6,70	-	-	-	-	0,8757
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	44	56,41	34	43,59	6,93	3,48	16,13	0,79	0,51	1,22	0,2838	0,8757
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	42	61,76	26	38,24	2,79	2,10	20,50	-	-	-	-	0,8757
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Race	Races other than White	SVd Arm	34	17	50,00	17	50,00	6,93	3,48	NA	0,63	0,32	1,24	0,1767	0,5139
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Race	Races other than White	Vd Arm	40	24	60,00	16	40,00	2,17	1,51	NA	-	-	-	-	0,5139
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Race	White	SVd Arm	158	94	59,49	64	40,51	4,63	3,48	8,38	0,81	0,60	1,08	0,1434	0,5139
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Race	White	Vd Arm	157	96	61,15	61	38,85	2,83	2,10	6,70	-	-	-	-	0,5139
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	3	60,00	2	40,00	4,06	3,48	NA	1,76	0,16	19,57	0,6419	0,5543
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	1,45	0,72	NA	-	-	-	-	0,5543
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	169	97	57,40	72	42,60	5,59	3,48	8,38	0,85	0,64	1,12	0,2391	0,5543
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	107	59,44	73	40,56	3,25	2,14	6,70	-	-	-	-	0,5543
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior PI therapies	N	SVd Arm	46	24	52,17	22	47,83	6,93	3,71	NA	0,67	0,39	1,17	0,1579	0,4958
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior PI therapies	N	Vd Arm	46	29	63,04	17	36,96	2,79	2,10	NA	-	-	-	-	0,4958
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior PI therapies	Y	SVd Arm	146	87	59,59	59	40,41	3,94	3,48	8,15	0,84	0,62	1,13	0,2378	0,4958
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior PI therapies	Y	Vd Arm	151	91	60,26	60	39,74	2,83	2,10	6,70	-	-	-	-	0,4958
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior anti-MM regimen	>1	SVd Arm	97	57	58,76	40	41,24	3,52	2,56	8,38	0,84	0,58	1,21	0,3378	0,7051
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior anti-MM regimen	>1	Vd Arm	101	62	61,39	39	38,61	2,79	2,10	6,90	-	-	-	-	0,7051
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior anti-MM regimen	1	SVd Arm	95	54	56,84	41	43,16	5,78	3,71	12,68	0,76	0,52	1,10	0,1434	0,7051
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior anti-MM regimen	1	Vd Arm	96	58	60,42	38	39,58	3,25	2,10	7,00	-	-	-	-	0,7051
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline single cytogenetic alterations	N	SVd Arm	96	56	58,33	40	41,67	5,75	3,48	8,51	0,74	0,52	1,06	0,1034	0,6341
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline single cytogenetic alterations	N	Vd Arm	106	68	64,15	38	35,85	2,17	1,74	4,86	-	-	-	-	0,6341
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	55	57,29	41	42,71	4,63	3,48	10,38	0,84	0,57	1,25	0,3924	0,6341
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Baseline single cytogenetic alterations	Y	Vd Arm	91	52	57,14	39	42,86	4,14	2,10	11,27	-	-	-	-	0,6341
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior Bortezomib exposure	N	SVd Arm	59	34	57,63	25	42,37	6,01	3,48	16,13	0,73	0,45	1,18	0,2002	0,7589
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior Bortezomib exposure	N	Vd Arm	60	37	61,67	23	38,33	2,79	1,45	NA	-	-	-	-	0,7589
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior Bortezomib exposure	Y	SVd Arm	133	77	57,89	56	42,11	4,63	3,48	8,38	0,80	0,58	1,09	0,1589	0,7589

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Dyspnoea Score	Prior Bortezomib exposure	Y	Vd Arm	137	83	60,58	54	39,42	2,83	2,10	6,90	-	-	-	-	0,7589
EORTC QLQ-C30 Symptom Items Constipation Score	total	-	SVd Arm	191	110	57,59	81	42,41	4,60	3,48	6,93	1,02	0,78	1,34	0,8631	NA
EORTC QLQ-C30 Symptom Items Constipation Score	total	-	Vd Arm	196	104	53,06	92	46,94	4,86	3,25	12,45	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Constipation Score	Gender	Female	SVd Arm	78	48	61,54	30	38,46	3,71	3,48	7,00	1,11	0,71	1,71	0,6509	0,5321
EORTC QLQ-C30 Symptom Items Constipation Score	Gender	Female	Vd Arm	85	42	49,41	43	50,59	5,16	3,19	NA	-	-	-	-	0,5321
EORTC QLQ-C30 Symptom Items Constipation Score	Gender	Male	SVd Arm	113	62	54,87	51	45,13	4,60	3,48	10,32	0,92	0,65	1,32	0,6643	0,5321
EORTC QLQ-C30 Symptom Items Constipation Score	Gender	Male	Vd Arm	111	62	55,86	49	44,14	4,24	2,20	12,45	-	-	-	-	0,5321
EORTC QLQ-C30 Symptom Items Constipation Score	Age Group	<65	SVd Arm	85	48	56,47	37	43,53	5,75	3,48	10,32	1,37	0,86	2,20	0,1855	0,1326
EORTC QLQ-C30 Symptom Items Constipation Score	Age Group	<65	Vd Arm	74	30	40,54	44	59,46	NA	4,17	NA	-	-	-	-	0,1326
EORTC QLQ-C30 Symptom Items Constipation Score	Age Group	>=65	SVd Arm	106	62	58,49	44	41,51	3,48	3,48	6,93	0,88	0,62	1,24	0,4558	0,1326
EORTC QLQ-C30 Symptom Items Constipation Score	Age Group	>=65	Vd Arm	122	74	60,66	48	39,34	3,45	2,17	9,00	-	-	-	-	0,1326
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline R-ISS stage	Stage I or II	SVd Arm	169	97	57,40	72	42,60	4,60	3,48	6,93	1,02	0,77	1,37	0,8703	0,5723
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline R-ISS stage	Stage I or II	Vd Arm	167	90	53,89	77	46,11	4,86	3,48	12,45	-	-	-	-	0,5723
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline R-ISS stage	Stage III	SVd Arm	12	8	66,67	4	33,33	5,75	1,41	NA	1,43	0,46	4,43	0,5306	0,5723
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline R-ISS stage	Stage III	Vd Arm	15	6	40,00	9	60,00	NA	2,10	NA	-	-	-	-	0,5723
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline ISS stage	Stage I or II	SVd Arm	159	94	59,12	65	40,88	3,94	3,48	5,78	1,10	0,82	1,48	0,5290	0,9946
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline ISS stage	Stage I or II	Vd Arm	166	88	53,01	78	46,99	4,86	3,45	12,45	-	-	-	-	0,9946
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline ISS stage	Stage III	SVd Arm	32	16	50,00	16	50,00	6,93	3,48	NA	1,10	0,53	2,29	0,7944	0,9946
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline ISS stage	Stage III	Vd Arm	30	16	53,33	14	46,67	15,90	2,07	NA	-	-	-	-	0,9946
EORTC QLQ-C30 Symptom Items Constipation Score	Region (SAP)	Region 1	SVd Arm	18	10	55,56	8	44,44	1,41	1,18	NA	1,22	0,43	3,42	0,7082	0,5227
EORTC QLQ-C30 Symptom Items Constipation Score	Region (SAP)	Region 1	Vd Arm	17	12	70,59	5	29,41	2,10	1,08	NA	-	-	-	-	0,5227
EORTC QLQ-C30 Symptom Items Constipation Score	Region (SAP)	Region 2	SVd Arm	58	32	55,17	26	44,83	3,48	2,33	NA	0,91	0,54	1,51	0,7060	0,5227
EORTC QLQ-C30 Symptom Items Constipation Score	Region (SAP)	Region 2	Vd Arm	58	31	53,45	27	46,55	3,45	1,68	NA	-	-	-	-	0,5227
EORTC QLQ-C30 Symptom Items Constipation Score	Region (SAP)	Region 3	SVd Arm	46	26	56,52	20	43,48	5,78	3,48	NA	0,79	0,44	1,41	0,4223	0,5227
EORTC QLQ-C30 Symptom Items Constipation Score	Region (SAP)	Region 3	Vd Arm	51	25	49,02	26	50,98	4,86	3,02	NA	-	-	-	-	0,5227
EORTC QLQ-C30 Symptom Items Constipation Score	Region (SAP)	Region 4	SVd Arm	69	42	60,87	27	39,13	4,67	3,48	8,28	1,32	0,83	2,11	0,2410	0,5227
EORTC QLQ-C30 Symptom Items Constipation Score	Region (SAP)	Region 4	Vd Arm	70	36	51,43	34	48,57	12,45	4,14	NA	-	-	-	-	0,5227
EORTC QLQ-C30 Symptom Items Constipation Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	113	64	56,64	49	43,36	4,60	2,33	9,56	0,88	0,62	1,25	0,4820	0,2000
EORTC QLQ-C30 Symptom Items Constipation Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	128	70	54,69	58	45,31	4,14	2,17	11,27	-	-	-	-	0,2000
EORTC QLQ-C30 Symptom Items Constipation Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	46	58,97	32	41,03	4,63	3,48	7,00	1,29	0,81	2,06	0,2814	0,2000

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Constipation Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	34	50,00	34	50,00	12,45	4,14	NA	-	-	-	-	0,2000
EORTC QLQ-C30 Symptom Items Constipation Score	Race	Races other than White	SVd Arm	34	22	64,71	12	35,29	3,48	2,04	10,32	1,71	0,85	3,45	0,1308	0,0554
EORTC QLQ-C30 Symptom Items Constipation Score	Race	Races other than White	Vd Arm	40	14	35,00	26	65,00	NA	11,27	NA	-	-	-	-	0,0554
EORTC QLQ-C30 Symptom Items Constipation Score	Race	White	SVd Arm	157	88	56,05	69	43,95	4,63	3,48	7,00	0,81	0,60	1,09	0,1683	0,0554
EORTC QLQ-C30 Symptom Items Constipation Score	Race	White	Vd Arm	156	90	57,69	66	42,31	4,14	2,37	7,20	-	-	-	-	0,0554
EORTC QLQ-C30 Symptom Items Constipation Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	4	3	75,00	1	25,00	3,48	1,15	NA	0,39	0,03	4,44	0,4328	0,4020
EORTC QLQ-C30 Symptom Items Constipation Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	3,45	0,72	NA	-	-	-	-	0,4020
EORTC QLQ-C30 Symptom Items Constipation Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	169	98	57,99	71	42,01	4,60	3,48	6,93	1,11	0,83	1,48	0,4709	0,4020
EORTC QLQ-C30 Symptom Items Constipation Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	179	93	51,96	86	48,04	5,16	3,71	18,76	-	-	-	-	0,4020
EORTC QLQ-C30 Symptom Items Constipation Score	Prior PI therapies	N	SVd Arm	46	24	52,17	22	47,83	4,60	3,48	NA	1,38	0,76	2,51	0,2841	0,2662
EORTC QLQ-C30 Symptom Items Constipation Score	Prior PI therapies	N	Vd Arm	46	21	45,65	25	54,35	12,45	5,16	NA	-	-	-	-	0,2662
EORTC QLQ-C30 Symptom Items Constipation Score	Prior PI therapies	Y	SVd Arm	145	86	59,31	59	40,69	4,60	3,48	7,00	0,95	0,70	1,28	0,7216	0,2662
EORTC QLQ-C30 Symptom Items Constipation Score	Prior PI therapies	Y	Vd Arm	150	83	55,33	67	44,67	4,14	2,17	15,90	-	-	-	-	0,2662
EORTC QLQ-C30 Symptom Items Constipation Score	Prior anti-MM regimen	>1	SVd Arm	97	60	61,86	37	38,14	3,48	2,33	7,00	1,30	0,89	1,92	0,1741	0,0787
EORTC QLQ-C30 Symptom Items Constipation Score	Prior anti-MM regimen	>1	Vd Arm	101	49	48,51	52	51,49	8,61	2,79	NA	-	-	-	-	0,0787
EORTC QLQ-C30 Symptom Items Constipation Score	Prior anti-MM regimen	1	SVd Arm	94	50	53,19	44	46,81	5,75	3,48	26,45	0,80	0,54	1,18	0,2566	0,0787
EORTC QLQ-C30 Symptom Items Constipation Score	Prior anti-MM regimen	1	Vd Arm	95	55	57,89	40	42,11	4,14	2,79	12,45	-	-	-	-	0,0787
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline single cytogenetic alterations	N	SVd Arm	96	55	57,29	41	42,71	5,75	3,48	8,28	1,13	0,77	1,66	0,5327	0,4299
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline single cytogenetic alterations	N	Vd Arm	105	53	50,48	52	49,52	6,60	3,45	NA	-	-	-	-	0,4299
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline single cytogenetic alterations	Y	SVd Arm	95	55	57,89	40	42,11	4,30	2,33	7,00	0,91	0,61	1,34	0,6212	0,4299
EORTC QLQ-C30 Symptom Items Constipation Score	Baseline single cytogenetic alterations	Y	Vd Arm	91	51	56,04	40	43,96	4,24	2,79	12,45	-	-	-	-	0,4299
EORTC QLQ-C30 Symptom Items Constipation Score	Prior Bortezomib exposure	N	SVd Arm	59	31	52,54	28	47,46	4,63	3,48	NA	1,12	0,67	1,88	0,6600	0,6766
EORTC QLQ-C30 Symptom Items Constipation Score	Prior Bortezomib exposure	N	Vd Arm	60	31	51,67	29	48,33	6,70	3,25	NA	-	-	-	-	0,6766
EORTC QLQ-C30 Symptom Items Constipation Score	Prior Bortezomib exposure	Y	SVd Arm	132	79	59,85	53	40,15	4,60	3,48	7,00	0,99	0,71	1,36	0,9329	0,6766
EORTC QLQ-C30 Symptom Items Constipation Score	Prior Bortezomib exposure	Y	Vd Arm	136	73	53,68	63	46,32	4,17	2,37	18,76	-	-	-	-	0,6766
EORTC QLQ-C30 Symptom Items Insomnia Score	total	-	SVd Arm	190	110	57,89	80	42,11	4,83	3,48	8,54	0,85	0,65	1,11	0,2281	NA
EORTC QLQ-C30 Symptom Items Insomnia Score	total	-	Vd Arm	195	119	61,03	76	38,97	3,48	2,79	6,87	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Insomnia Score	Gender	Female	SVd Arm	78	42	53,85	36	46,15	8,08	3,48	14,06	0,78	0,50	1,20	0,2568	0,7223
EORTC QLQ-C30 Symptom Items Insomnia Score	Gender	Female	Vd Arm	84	47	55,95	37	44,05	4,63	2,79	22,83	-	-	-	-	0,7223

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Insomnia Score	Gender	Male	SVd Arm	112	68	60,71	44	39,29	3,71	2,33	8,51	0,86	0,61	1,21	0,3835	0,7223
EORTC QLQ-C30 Symptom Items Insomnia Score	Gender	Male	Vd Arm	111	72	64,86	39	35,14	3,25	2,79	4,93	-	-	-	-	0,7223
EORTC QLQ-C30 Symptom Items Insomnia Score	Age Group	<65	SVd Arm	85	51	60,00	34	40,00	3,48	2,33	14,06	0,98	0,64	1,51	0,9244	0,4547
EORTC QLQ-C30 Symptom Items Insomnia Score	Age Group	<65	Vd Arm	74	39	52,70	35	47,30	4,17	3,06	NA	-	-	-	-	0,4547
EORTC QLQ-C30 Symptom Items Insomnia Score	Age Group	>=65	SVd Arm	105	59	56,19	46	43,81	6,93	3,48	10,41	0,79	0,56	1,12	0,1870	0,4547
EORTC QLQ-C30 Symptom Items Insomnia Score	Age Group	>=65	Vd Arm	121	80	66,12	41	33,88	3,02	2,17	5,16	-	-	-	-	0,4547
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline R-ISS stage	Stage I or II	SVd Arm	168	99	58,93	69	41,07	4,86	3,48	8,54	0,87	0,66	1,15	0,3303	0,9117
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline R-ISS stage	Stage I or II	Vd Arm	166	101	60,84	65	39,16	3,48	2,83	7,85	-	-	-	-	0,9117
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline R-ISS stage	Stage III	SVd Arm	12	7	58,33	5	41,67	2,37	1,18	NA	0,93	0,32	2,69	0,8879	0,9117
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline R-ISS stage	Stage III	Vd Arm	15	10	66,67	5	33,33	4,21	2,10	NA	-	-	-	-	0,9117
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline ISS stage	Stage I or II	SVd Arm	158	90	56,96	68	43,04	4,83	3,48	10,41	0,86	0,65	1,14	0,2990	0,9466
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline ISS stage	Stage I or II	Vd Arm	165	101	61,21	64	38,79	3,48	2,83	6,87	-	-	-	-	0,9466
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline ISS stage	Stage III	SVd Arm	32	20	62,50	12	37,50	2,40	1,41	NA	0,88	0,45	1,71	0,7077	0,9466
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline ISS stage	Stage III	Vd Arm	30	18	60,00	12	40,00	2,89	2,10	NA	-	-	-	-	0,9466
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (SAP)	Region 1	SVd Arm	18	10	55,56	8	44,44	4,76	1,18	NA	0,88	0,31	2,46	0,8041	0,5856
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (SAP)	Region 1	Vd Arm	17	10	58,82	7	41,18	3,06	0,82	NA	-	-	-	-	0,5856
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (SAP)	Region 2	SVd Arm	57	29	50,88	28	49,12	6,97	2,40	NA	0,70	0,42	1,17	0,1734	0,5856
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (SAP)	Region 2	Vd Arm	58	35	60,34	23	39,66	2,79	1,68	7,20	-	-	-	-	0,5856
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (SAP)	Region 3	SVd Arm	46	30	65,22	16	34,78	4,86	3,48	13,93	0,73	0,43	1,22	0,2254	0,5856
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (SAP)	Region 3	Vd Arm	51	32	62,75	19	37,25	3,71	2,10	7,85	-	-	-	-	0,5856
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (SAP)	Region 4	SVd Arm	69	41	59,42	28	40,58	4,70	2,33	19,58	1,07	0,69	1,68	0,7589	0,5856
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (SAP)	Region 4	Vd Arm	69	42	60,87	27	39,13	6,87	2,89	22,83	-	-	-	-	0,5856
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	112	62	55,36	50	44,64	6,01	3,48	11,50	0,79	0,56	1,11	0,1764	0,3051
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	127	75	59,06	52	40,94	3,71	2,79	7,85	-	-	-	-	0,3051
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	48	61,54	30	38,46	3,48	2,04	12,68	1,05	0,69	1,60	0,8250	0,3051
EORTC QLQ-C30 Symptom Items Insomnia Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	44	64,71	24	35,29	3,48	2,79	20,50	-	-	-	-	0,3051
EORTC QLQ-C30 Symptom Items Insomnia Score	Race	Races other than White	SVd Arm	34	15	44,12	19	55,88	10,41	2,60	NA	0,92	0,46	1,83	0,8030	0,8431
EORTC QLQ-C30 Symptom Items Insomnia Score	Race	Races other than White	Vd Arm	40	22	55,00	18	45,00	11,27	2,89	NA	-	-	-	-	0,8431
EORTC QLQ-C30 Symptom Items Insomnia Score	Race	White	SVd Arm	156	95	60,90	61	39,10	4,67	3,48	8,51	0,85	0,63	1,14	0,2698	0,8431
EORTC QLQ-C30 Symptom Items Insomnia Score	Race	White	Vd Arm	155	97	62,58	58	37,42	3,25	2,79	5,09	-	-	-	-	0,8431

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Insomnia Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	4	1	25,00	3	75,00	24,15	NA	NA	NA	NA	NA	1,0000	NA
EORTC QLQ-C30 Symptom Items Insomnia Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	4,21	1,41	NA	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Insomnia Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	168	98	58,33	70	41,67	4,83	3,48	8,54	0,88	0,67	1,17	0,3764	NA
EORTC QLQ-C30 Symptom Items Insomnia Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	178	107	60,11	71	39,89	3,94	2,89	7,85	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior PI therapies	N	SVd Arm	46	27	58,70	19	41,30	6,93	2,33	19,58	0,79	0,46	1,35	0,3802	0,7443
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior PI therapies	N	Vd Arm	46	32	69,57	14	30,43	3,25	2,10	10,15	-	-	-	-	0,7443
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior PI therapies	Y	SVd Arm	144	83	57,64	61	42,36	4,83	3,48	8,54	0,87	0,64	1,18	0,3746	0,7443
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior PI therapies	Y	Vd Arm	149	87	58,39	62	41,61	3,48	2,79	10,32	-	-	-	-	0,7443
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior anti-MM regimen	>1	SVd Arm	97	55	56,70	42	43,30	6,93	2,60	13,93	0,71	0,50	1,03	0,0672	0,1649
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior anti-MM regimen	>1	Vd Arm	99	68	68,69	31	31,31	3,12	2,10	4,63	-	-	-	-	0,1649
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior anti-MM regimen	1	SVd Arm	93	55	59,14	38	40,86	4,76	3,48	10,45	1,04	0,71	1,53	0,8448	0,1649
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior anti-MM regimen	1	Vd Arm	96	51	53,12	45	46,88	4,07	2,79	NA	-	-	-	-	0,1649
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline single cytogenetic alterations	N	SVd Arm	95	53	55,79	42	44,21	6,93	3,45	14,06	0,83	0,57	1,20	0,3201	0,9522
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline single cytogenetic alterations	N	Vd Arm	106	65	61,32	41	38,68	4,17	3,06	7,85	-	-	-	-	0,9522
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline single cytogenetic alterations	Y	SVd Arm	95	57	60,00	38	40,00	3,71	2,40	10,45	0,84	0,57	1,24	0,3793	0,9522
EORTC QLQ-C30 Symptom Items Insomnia Score	Baseline single cytogenetic alterations	Y	Vd Arm	89	54	60,67	35	39,33	2,79	2,10	10,32	-	-	-	-	0,9522
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior Bortezomib exposure	N	SVd Arm	59	34	57,63	25	42,37	4,70	2,40	16,20	0,74	0,45	1,19	0,2107	0,3416
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior Bortezomib exposure	N	Vd Arm	60	42	70,00	18	30,00	2,79	1,41	7,20	-	-	-	-	0,3416
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior Bortezomib exposure	Y	SVd Arm	131	76	58,02	55	41,98	4,83	3,48	8,54	0,97	0,71	1,34	0,8728	0,3416
EORTC QLQ-C30 Symptom Items Insomnia Score	Prior Bortezomib exposure	Y	Vd Arm	135	77	57,04	58	42,96	4,17	2,89	11,27	-	-	-	-	0,3416
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	total	-	SVd Arm	190	79	41,58	111	58,42	16,16	8,28	NA	0,97	0,71	1,33	0,8468	NA
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	total	-	Vd Arm	194	81	41,75	113	58,25	21,29	9,26	NA	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Gender	Female	SVd Arm	78	30	38,46	48	61,54	23,00	9,23	NA	0,95	0,55	1,64	0,8427	0,9982
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Gender	Female	Vd Arm	83	30	36,14	53	63,86	NA	14,78	NA	-	-	-	-	0,9982
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Gender	Male	SVd Arm	112	49	43,75	63	56,25	10,41	6,18	NA	0,95	0,64	1,41	0,7811	0,9982
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Gender	Male	Vd Arm	111	51	45,95	60	54,05	11,10	5,55	NA	-	-	-	-	0,9982
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Age Group	<65	SVd Arm	84	40	47,62	44	52,38	8,28	5,78	NA	1,33	0,80	2,20	0,2689	0,0802

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Age Group	<65	Vd Arm	74	28	37,84	46	62,16	28,25	9,26	NA	-	-	-	-	0,0802
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Age Group	>=65	SVd Arm	106	39	36,79	67	63,21	18,43	10,38	NA	0,74	0,49	1,12	0,1569	0,0802
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Age Group	>=65	Vd Arm	120	53	44,17	67	55,83	20,30	7,20	NA	-	-	-	-	0,0802
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline R-ISS stage	Stage I or II	SVd Arm	169	67	39,64	102	60,36	18,43	9,23	NA	0,82	0,59	1,14	0,2371	0,0263
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline R-ISS stage	Stage I or II	Vd Arm	165	73	44,24	92	55,76	20,30	7,72	NA	-	-	-	-	0,0263
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline R-ISS stage	Stage III	SVd Arm	12	9	75,00	3	25,00	3,58	1,41	NA	4,02	1,03	15,74	0,0342	0,0263
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline R-ISS stage	Stage III	Vd Arm	15	5	33,33	10	66,67	NA	9,26	NA	-	-	-	-	0,0263
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline ISS stage	Stage I or II	SVd Arm	158	62	39,24	96	60,76	23,00	10,38	NA	0,93	0,66	1,32	0,6860	0,6439
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline ISS stage	Stage I or II	Vd Arm	164	66	40,24	98	59,76	22,70	11,10	NA	-	-	-	-	0,6439
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline ISS stage	Stage III	SVd Arm	32	17	53,12	15	46,88	5,85	3,71	NA	1,12	0,55	2,31	0,7503	0,6439
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline ISS stage	Stage III	Vd Arm	30	15	50,00	15	50,00	9,26	2,30	NA	-	-	-	-	0,6439
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (SAP)	Region 1	SVd Arm	18	4	22,22	14	77,78	NA	NA	NA	0,35	0,10	1,20	0,0820	0,2104
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (SAP)	Region 1	Vd Arm	17	9	52,94	8	47,06	7,72	2,10	NA	-	-	-	-	0,2104
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (SAP)	Region 2	SVd Arm	58	23	39,66	35	60,34	18,43	5,78	NA	1,34	0,70	2,58	0,3712	0,2104
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (SAP)	Region 2	Vd Arm	58	17	29,31	41	70,69	NA	22,70	NA	-	-	-	-	0,2104
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (SAP)	Region 3	SVd Arm	45	22	48,89	23	51,11	7,62	4,30	NA	0,72	0,40	1,29	0,2654	0,2104
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (SAP)	Region 3	Vd Arm	50	28	56,00	22	44,00	4,50	3,25	NA	-	-	-	-	0,2104
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (SAP)	Region 4	SVd Arm	69	30	43,48	39	56,52	10,41	8,28	NA	1,03	0,60	1,77	0,9183	0,2104
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (SAP)	Region 4	Vd Arm	69	27	39,13	42	60,87	28,25	14,78	NA	-	-	-	-	0,2104
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	112	45	40,18	67	59,82	16,16	7,62	NA	0,88	0,59	1,32	0,5436	0,4253
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	126	56	44,44	70	55,56	11,10	6,01	NA	-	-	-	-	0,4253
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	34	43,59	44	56,41	10,41	8,28	NA	1,16	0,68	1,98	0,5884	0,4253

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	25	36,76	43	63,24	28,25	14,78	NA	-	-	-	-	0,4253
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Race	Races other than White	SVd Arm	34	17	50,00	17	50,00	5,91	3,48	NA	1,55	0,73	3,29	0,2508	0,1685
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Race	Races other than White	Vd Arm	40	15	37,50	25	62,50	28,25	9,26	NA	-	-	-	-	0,1685
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Race	White	SVd Arm	156	62	39,74	94	60,26	18,43	10,38	NA	0,86	0,61	1,23	0,4177	0,1685
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Race	White	Vd Arm	154	66	42,86	88	57,14	20,30	7,20	NA	-	-	-	-	0,1685
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	-	-	-	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	167	69	41,32	98	58,68	16,16	8,02	NA	0,92	0,66	1,29	0,6390	NA
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	177	78	44,07	99	55,93	20,30	8,61	NA	-	-	-	-	NA
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior PI therapies	N	SVd Arm	46	16	34,78	30	65,22	23,03	10,38	NA	0,79	0,40	1,55	0,4879	0,4956
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior PI therapies	N	Vd Arm	46	21	45,65	25	54,35	12,42	5,16	NA	-	-	-	-	0,4956
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior PI therapies	Y	SVd Arm	144	63	43,75	81	56,25	10,41	7,62	NA	1,03	0,72	1,47	0,8819	0,4956
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior PI therapies	Y	Vd Arm	148	60	40,54	88	59,46	21,29	9,26	NA	-	-	-	-	0,4956
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior anti-MM regimen	>1	SVd Arm	96	34	35,42	62	64,58	NA	8,28	NA	0,79	0,50	1,25	0,3226	0,2369
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior anti-MM regimen	>1	Vd Arm	99	42	42,42	57	57,58	28,25	7,72	NA	-	-	-	-	0,2369
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior anti-MM regimen	1	SVd Arm	94	45	47,87	49	52,13	10,38	6,18	23,43	1,16	0,75	1,80	0,4966	0,2369
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior anti-MM regimen	1	Vd Arm	95	39	41,05	56	58,95	21,29	9,00	NA	-	-	-	-	0,2369
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline single cytogenetic alterations	N	SVd Arm	94	44	46,81	50	53,19	9,23	6,18	NA	1,19	0,78	1,83	0,4131	0,1229
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline single cytogenetic alterations	N	Vd Arm	105	43	40,95	62	59,05	28,25	9,00	NA	-	-	-	-	0,1229
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	35	36,46	61	63,54	23,03	8,02	NA	0,72	0,45	1,16	0,1789	0,1229
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Baseline single cytogenetic alterations	Y	Vd Arm	89	38	42,70	51	57,30	14,78	7,72	NA	-	-	-	-	0,1229
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior Bortezomib exposure	N	SVd Arm	58	20	34,48	38	65,52	23,03	10,38	NA	0,83	0,45	1,55	0,5634	0,5478

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior Bortezomib exposure	N	Vd Arm	60	26	43,33	34	56,67	28,25	5,16	NA	-	-	-	-	0,5478
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior Bortezomib exposure	Y	SVd Arm	132	59	44,70	73	55,30	10,41	7,62	NA	1,04	0,72	1,51	0,8361	0,5478
EORTC QLQ-C30 Symptom Items Financial Difficulties Score	Prior Bortezomib exposure	Y	Vd Arm	134	55	41,04	79	58,96	21,29	9,26	NA	-	-	-	-	0,5478
EORTC QLQ-C30 Functional Scales Physical Functioning Score	total	-	SVd Arm	192	90	46,88	102	53,12	9,43	6,93	18,43	0,80	0,60	1,07	0,1272	NA
EORTC QLQ-C30 Functional Scales Physical Functioning Score	total	-	Vd Arm	197	101	51,27	96	48,73	6,70	4,17	13,60	-	-	-	-	NA
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Gender	Female	SVd Arm	78	41	52,56	37	47,44	6,93	4,70	NA	1,21	0,75	1,93	0,4328	0,0257
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Gender	Female	Vd Arm	86	39	45,35	47	54,65	11,27	5,16	NA	-	-	-	-	0,0257
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Gender	Male	SVd Arm	114	49	42,98	65	57,02	11,56	7,62	NA	0,60	0,41	0,89	0,0099	0,0257
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Gender	Male	Vd Arm	111	62	55,86	49	44,14	3,94	2,83	10,15	-	-	-	-	0,0257
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Age Group	<65	SVd Arm	85	37	43,53	48	56,47	12,68	7,16	NA	0,94	0,57	1,56	0,8187	0,3990
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Age Group	<65	Vd Arm	74	30	40,54	44	59,46	20,57	5,78	NA	-	-	-	-	0,3990
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Age Group	>=65	SVd Arm	107	53	49,53	54	50,47	9,13	5,78	13,93	0,72	0,50	1,04	0,0807	0,3990
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Age Group	>=65	Vd Arm	123	71	57,72	52	42,28	4,86	3,48	10,15	-	-	-	-	0,3990
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline R-ISS stage	Stage I or II	SVd Arm	170	81	47,65	89	52,35	10,38	6,93	18,43	0,79	0,59	1,08	0,1354	0,1996
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline R-ISS stage	Stage I or II	Vd Arm	168	87	51,79	81	48,21	5,88	4,14	11,27	-	-	-	-	0,1996
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline R-ISS stage	Stage III	SVd Arm	12	7	58,33	5	41,67	3,68	1,25	NA	1,89	0,52	6,86	0,3278	0,1996
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline R-ISS stage	Stage III	Vd Arm	15	5	33,33	10	66,67	29,70	NA	NA	-	-	-	-	0,1996
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline ISS stage	Stage I or II	SVd Arm	160	72	45,00	88	55,00	10,41	7,62	26,84	0,75	0,55	1,02	0,0694	0,1421
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline ISS stage	Stage I or II	Vd Arm	167	87	52,10	80	47,90	5,32	3,94	11,27	-	-	-	-	0,1421
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline ISS stage	Stage III	SVd Arm	32	18	56,25	14	43,75	6,93	3,52	NA	1,36	0,65	2,83	0,4094	0,1421
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline ISS stage	Stage III	Vd Arm	30	14	46,67	16	53,33	21,29	2,79	NA	-	-	-	-	0,1421
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (SAP)	Region 1	SVd Arm	18	7	38,89	11	61,11	18,43	3,68	NA	0,52	0,14	1,90	0,3128	0,2191

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (SAP)	Region 1	Vd Arm	17	8	47,06	9	52,94	11,27	2,07	NA	-	-	-	-	0,2191
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (SAP)	Region 2	SVd Arm	59	28	47,46	31	52,54	9,43	3,48	NA	0,97	0,57	1,65	0,9013	0,2191
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (SAP)	Region 2	Vd Arm	58	29	50,00	29	50,00	5,88	2,79	NA	-	-	-	-	0,2191
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (SAP)	Region 3	SVd Arm	46	21	45,65	25	54,35	9,20	6,01	NA	0,46	0,26	0,83	0,0083	0,2191
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (SAP)	Region 3	Vd Arm	52	31	59,62	21	40,38	4,17	3,25	10,12	-	-	-	-	0,2191
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (SAP)	Region 4	SVd Arm	69	34	49,28	35	50,72	10,38	6,47	NA	0,92	0,56	1,50	0,7242	0,2191
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (SAP)	Region 4	Vd Arm	70	33	47,14	37	52,86	20,57	4,86	NA	-	-	-	-	0,2191
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	114	50	43,86	64	56,14	10,38	6,93	NA	0,73	0,50	1,06	0,1003	0,4612
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	66	51,16	63	48,84	5,88	3,94	13,60	-	-	-	-	0,4612
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	40	51,28	38	48,72	9,13	5,13	26,84	0,91	0,57	1,46	0,7013	0,4612
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	35	51,47	33	48,53	7,89	3,19	NA	-	-	-	-	0,4612
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Race	Races other than White	SVd Arm	34	16	47,06	18	52,94	12,68	4,67	NA	0,87	0,42	1,81	0,7100	0,7294
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Race	Races other than White	Vd Arm	40	18	45,00	22	55,00	11,27	2,79	NA	-	-	-	-	0,7294
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Race	White	SVd Arm	158	74	46,84	84	53,16	9,43	7,16	23,03	0,76	0,55	1,04	0,0889	0,7294
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Race	White	Vd Arm	157	83	52,87	74	47,13	5,88	4,14	13,60	-	-	-	-	0,7294
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	9,13	3,48	NA	2,73	0,28	26,42	0,3657	0,2961
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	NA	1,45	NA	-	-	-	-	0,2961
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	169	79	46,75	90	53,25	10,38	6,93	26,55	0,81	0,59	1,10	0,1683	0,2961
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	92	51,11	88	48,89	6,70	4,17	20,57	-	-	-	-	0,2961
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior PI therapies	N	SVd Arm	46	25	54,35	21	45,65	8,54	3,55	NA	0,98	0,56	1,73	0,9569	0,3969
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior PI therapies	N	Vd Arm	46	26	56,52	20	43,48	6,70	3,25	NA	-	-	-	-	0,3969
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior PI therapies	Y	SVd Arm	146	65	44,52	81	55,48	11,53	7,16	26,84	0,74	0,53	1,04	0,0810	0,3969

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior PI therapies	Y	Vd Arm	151	75	49,67	76	50,33	6,70	4,07	21,29	-	-	-	-	0,3969
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior anti-MM regimen	>1	SVd Arm	97	45	46,39	52	53,61	12,68	6,01	NA	0,65	0,44	0,97	0,0348	0,1458
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior anti-MM regimen	>1	Vd Arm	101	57	56,44	44	43,56	4,86	3,06	7,89	-	-	-	-	0,1458
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior anti-MM regimen	1	SVd Arm	95	45	47,37	50	52,63	9,13	6,47	NA	1,00	0,66	1,53	0,9829	0,1458
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior anti-MM regimen	1	Vd Arm	96	44	45,83	52	54,17	13,60	4,86	NA	-	-	-	-	0,1458
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline single cytogenetic alterations	N	SVd Arm	96	43	44,79	53	55,21	10,41	8,51	28,78	0,71	0,47	1,06	0,0916	0,5101
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline single cytogenetic alterations	N	Vd Arm	106	55	51,89	51	48,11	5,16	3,94	NA	-	-	-	-	0,5101
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	47	48,96	49	51,04	7,62	5,13	NA	0,86	0,56	1,31	0,4773	0,5101
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Baseline single cytogenetic alterations	Y	Vd Arm	91	46	50,55	45	49,45	7,89	3,52	NA	-	-	-	-	0,5101
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior Bortezomib exposure	N	SVd Arm	59	30	50,85	29	49,15	8,54	3,58	NA	0,86	0,52	1,43	0,5571	0,8359
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior Bortezomib exposure	N	Vd Arm	60	34	56,67	26	43,33	5,16	3,19	NA	-	-	-	-	0,8359
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior Bortezomib exposure	Y	SVd Arm	133	60	45,11	73	54,89	10,38	7,16	26,84	0,80	0,56	1,15	0,2283	0,8359
EORTC QLQ-C30 Functional Scales Physical Functioning Score	Prior Bortezomib exposure	Y	Vd Arm	137	67	48,91	70	51,09	7,03	4,17	NA	-	-	-	-	0,8359
EORTC QLQ-C30 Functional Scales Role Functioning Score	total	-	SVd Arm	192	144	75,00	48	25,00	3,45	2,33	3,52	0,85	0,67	1,07	0,1597	NA
EORTC QLQ-C30 Functional Scales Role Functioning Score	total	-	Vd Arm	196	145	73,98	51	26,02	2,10	1,41	2,79	-	-	-	-	NA
EORTC QLQ-C30 Functional Scales Role Functioning Score	Gender	Female	SVd Arm	78	59	75,64	19	24,36	3,48	2,33	4,67	0,86	0,59	1,26	0,4456	0,9189
EORTC QLQ-C30 Functional Scales Role Functioning Score	Gender	Female	Vd Arm	85	59	69,41	26	30,59	1,48	1,38	4,07	-	-	-	-	0,9189
EORTC QLQ-C30 Functional Scales Role Functioning Score	Gender	Male	SVd Arm	114	85	74,56	29	25,44	2,40	2,33	3,94	0,84	0,62	1,14	0,2666	0,9189
EORTC QLQ-C30 Functional Scales Role Functioning Score	Gender	Male	Vd Arm	111	86	77,48	25	22,52	2,17	1,48	3,06	-	-	-	-	0,9189
EORTC QLQ-C30 Functional Scales Role Functioning Score	Age Group	<65	SVd Arm	85	61	71,76	24	28,24	3,48	2,30	4,67	0,84	0,57	1,25	0,3976	0,8271
EORTC QLQ-C30 Functional Scales Role Functioning Score	Age Group	<65	Vd Arm	74	49	66,22	25	33,78	2,17	1,41	4,17	-	-	-	-	0,8271
EORTC QLQ-C30 Functional Scales Role Functioning Score	Age Group	>=65	SVd Arm	107	83	77,57	24	22,43	2,40	2,33	3,52	0,89	0,66	1,21	0,4605	0,8271
EORTC QLQ-C30 Functional Scales Role Functioning Score	Age Group	>=65	Vd Arm	122	96	78,69	26	21,31	2,10	1,41	2,83	-	-	-	-	0,8271
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline R-ISS stage	Stage I or II	SVd Arm	170	127	74,71	43	25,29	3,48	2,33	4,30	0,84	0,66	1,08	0,1762	0,1016
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline R-ISS stage	Stage I or II	Vd Arm	167	124	74,25	43	25,75	2,17	1,41	2,83	-	-	-	-	0,1016
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline R-ISS stage	Stage III	SVd Arm	12	12	100,00	0	0,00	1,87	1,18	NA	1,95	0,74	5,17	0,1729	0,1016

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline R-ISS stage	Stage III	Vd Arm	15	9	60,00	6	40,00	5,59	2,10	NA	-	-	-	-	0,1016
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline ISS stage	Stage I or II	SVd Arm	160	119	74,38	41	25,62	3,48	2,37	4,40	0,84	0,65	1,08	0,1767	0,3209
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline ISS stage	Stage I or II	Vd Arm	166	122	73,49	44	26,51	2,10	1,41	2,79	-	-	-	-	0,3209
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline ISS stage	Stage III	SVd Arm	32	25	78,12	7	21,88	2,33	1,25	5,75	1,17	0,64	2,15	0,6103	0,3209
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline ISS stage	Stage III	Vd Arm	30	23	76,67	7	23,33	2,10	1,41	6,70	-	-	-	-	0,3209
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (SAP)	Region 1	SVd Arm	18	13	72,22	5	27,78	1,41	1,18	NA	0,66	0,27	1,59	0,3516	0,9595
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (SAP)	Region 1	Vd Arm	17	14	82,35	3	17,65	1,38	0,72	NA	-	-	-	-	0,9595
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (SAP)	Region 2	SVd Arm	59	42	71,19	17	28,81	2,40	1,28	4,40	0,86	0,55	1,34	0,5016	0,9595
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (SAP)	Region 2	Vd Arm	58	44	75,86	14	24,14	1,41	1,41	3,48	-	-	-	-	0,9595
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (SAP)	Region 3	SVd Arm	46	42	91,30	4	8,70	3,48	2,40	4,63	0,80	0,51	1,26	0,3304	0,9595
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (SAP)	Region 3	Vd Arm	51	43	84,31	8	15,69	2,23	0,82	3,25	-	-	-	-	0,9595
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (SAP)	Region 4	SVd Arm	69	47	68,12	22	31,88	3,52	2,33	6,74	0,84	0,55	1,28	0,4137	0,9595
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (SAP)	Region 4	Vd Arm	70	44	62,86	26	37,14	2,79	2,10	6,90	-	-	-	-	0,9595
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	114	88	77,19	26	22,81	2,56	2,33	3,48	0,79	0,59	1,05	0,1073	0,3819
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	128	101	78,91	27	21,09	1,41	1,41	2,79	-	-	-	-	0,3819
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	56	71,79	22	28,21	3,48	2,33	5,75	0,98	0,66	1,48	0,9379	0,3819
EORTC QLQ-C30 Functional Scales Role Functioning Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	44	64,71	24	35,29	2,79	2,10	4,17	-	-	-	-	0,3819
EORTC QLQ-C30 Functional Scales Role Functioning Score	Race	Races other than White	SVd Arm	34	21	61,76	13	38,24	4,60	2,30	NA	0,64	0,34	1,19	0,1516	0,4070
EORTC QLQ-C30 Functional Scales Role Functioning Score	Race	Races other than White	Vd Arm	40	26	65,00	14	35,00	2,17	1,41	11,27	-	-	-	-	0,4070
EORTC QLQ-C30 Functional Scales Role Functioning Score	Race	White	SVd Arm	158	123	77,85	35	22,15	2,56	2,33	3,48	0,85	0,65	1,09	0,2025	0,4070
EORTC QLQ-C30 Functional Scales Role Functioning Score	Race	White	Vd Arm	156	119	76,28	37	23,72	2,10	1,41	2,79	-	-	-	-	0,4070
EORTC QLQ-C30 Functional Scales Role Functioning Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	3,48	1,18	NA	3,35	0,34	33,36	0,2769	0,2441
EORTC QLQ-C30 Functional Scales Role Functioning Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	1,38	0,72	NA	-	-	-	-	0,2441
EORTC QLQ-C30 Functional Scales Role Functioning Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	169	127	75,15	42	24,85	3,45	2,33	3,58	0,85	0,66	1,09	0,1894	0,2441
EORTC QLQ-C30 Functional Scales Role Functioning Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	179	133	74,30	46	25,70	2,17	1,48	2,83	-	-	-	-	0,2441
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior PI therapies	N	SVd Arm	46	33	71,74	13	28,26	3,48	2,33	7,39	0,82	0,50	1,34	0,4346	0,9027
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior PI therapies	N	Vd Arm	46	36	78,26	10	21,74	2,14	2,10	3,75	-	-	-	-	0,9027
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior PI therapies	Y	SVd Arm	146	111	76,03	35	23,97	2,76	2,33	3,52	0,85	0,65	1,11	0,2399	0,9027
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior PI therapies	Y	Vd Arm	150	109	72,67	41	27,33	2,10	1,41	2,83	-	-	-	-	0,9027

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior anti-MM regimen	>1	SVd Arm	97	69	71,13	28	28,87	2,56	2,33	4,40	0,82	0,59	1,15	0,2552	0,8335
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior anti-MM regimen	>1	Vd Arm	100	73	73,00	27	27,00	2,10	1,41	3,48	-	-	-	-	0,8335
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior anti-MM regimen	1	SVd Arm	95	75	78,95	20	21,05	3,48	2,33	4,63	0,87	0,62	1,21	0,3943	0,8335
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior anti-MM regimen	1	Vd Arm	96	72	75,00	24	25,00	2,14	1,41	3,22	-	-	-	-	0,8335
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline single cytogenetic alterations	N	SVd Arm	96	71	73,96	25	26,04	3,48	2,33	4,63	0,86	0,62	1,19	0,3521	0,9256
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline single cytogenetic alterations	N	Vd Arm	106	80	75,47	26	24,53	2,17	1,41	3,48	-	-	-	-	0,9256
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	73	76,04	23	23,96	2,76	2,33	3,52	0,84	0,59	1,18	0,3108	0,9256
EORTC QLQ-C30 Functional Scales Role Functioning Score	Baseline single cytogenetic alterations	Y	Vd Arm	90	65	72,22	25	27,78	2,10	1,41	3,25	-	-	-	-	0,9256
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior Bortezomib exposure	N	SVd Arm	59	41	69,49	18	30,51	2,40	2,33	6,74	0,80	0,52	1,25	0,3315	0,8426
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior Bortezomib exposure	N	Vd Arm	60	45	75,00	15	25,00	2,14	2,10	3,48	-	-	-	-	0,8426
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior Bortezomib exposure	Y	SVd Arm	133	103	77,44	30	22,56	3,45	2,33	3,58	0,85	0,64	1,12	0,2430	0,8426
EORTC QLQ-C30 Functional Scales Role Functioning Score	Prior Bortezomib exposure	Y	Vd Arm	136	100	73,53	36	26,47	2,10	1,41	2,83	-	-	-	-	0,8426
EORTC QLQ-C30 Functional Scales Emotional Functional Score	total	-	SVd Arm	190	103	54,21	87	45,79	5,59	4,63	10,38	1,00	0,76	1,32	0,9956	NA
EORTC QLQ-C30 Functional Scales Emotional Functional Score	total	-	Vd Arm	197	104	52,79	93	47,21	5,78	3,71	21,29	-	-	-	-	NA
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Gender	Female	SVd Arm	78	39	50,00	39	50,00	6,93	4,63	NA	0,91	0,58	1,43	0,6791	0,6430
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Gender	Female	Vd Arm	86	43	50,00	43	50,00	9,00	3,71	NA	-	-	-	-	0,6430
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Gender	Male	SVd Arm	112	64	57,14	48	42,86	4,67	3,68	10,38	1,04	0,73	1,49	0,8228	0,6430
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Gender	Male	Vd Arm	111	61	54,95	50	45,05	4,93	3,48	21,29	-	-	-	-	0,6430
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Age Group	<65	SVd Arm	84	54	64,29	30	35,71	3,68	2,40	6,47	1,62	1,03	2,56	0,0355	0,0126
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Age Group	<65	Vd Arm	74	33	44,59	41	55,41	6,70	3,71	NA	-	-	-	-	0,0126
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Age Group	>=65	SVd Arm	106	49	46,23	57	53,77	9,23	5,59	23,26	0,77	0,53	1,12	0,1633	0,0126
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Age Group	>=65	Vd Arm	123	71	57,72	52	42,28	4,86	3,48	21,29	-	-	-	-	0,0126
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline R-ISS stage	Stage I or II	SVd Arm	169	93	55,03	76	44,97	6,47	4,63	12,68	0,93	0,70	1,25	0,6429	0,0933
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline R-ISS stage	Stage I or II	Vd Arm	168	93	55,36	75	44,64	5,55	3,52	16,00	-	-	-	-	0,0933
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline R-ISS stage	Stage III	SVd Arm	12	8	66,67	4	33,33	3,60	2,33	NA	3,14	0,78	12,60	0,0924	0,0933

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline R-ISS stage	Stage III	Vd Arm	15	4	26,67	11	73,33	NA	NA	NA	-	-	-	-	0,0933
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline ISS stage	Stage I or II	SVd Arm	158	82	51,90	76	48,10	6,90	4,63	13,90	0,96	0,71	1,30	0,7739	0,4757
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline ISS stage	Stage I or II	Vd Arm	167	89	53,29	78	46,71	5,68	3,71	25,56	-	-	-	-	0,4757
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline ISS stage	Stage III	SVd Arm	32	21	65,62	11	34,38	4,63	2,33	NA	1,26	0,63	2,51	0,5130	0,4757
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline ISS stage	Stage III	Vd Arm	30	15	50,00	15	50,00	21,29	2,37	NA	-	-	-	-	0,4757
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (SAP)	Region 1	SVd Arm	18	9	50,00	9	50,00	3,94	2,30	NA	0,43	0,14	1,32	0,1306	0,3506
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (SAP)	Region 1	Vd Arm	17	11	64,71	6	35,29	3,71	2,10	NA	-	-	-	-	0,3506
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (SAP)	Region 2	SVd Arm	58	30	51,72	28	48,28	4,67	3,48	NA	1,00	0,60	1,68	0,9937	0,3506
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (SAP)	Region 2	Vd Arm	58	29	50,00	29	50,00	6,60	3,48	NA	-	-	-	-	0,3506
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (SAP)	Region 3	SVd Arm	45	26	57,78	19	42,22	7,62	4,63	NA	0,78	0,45	1,36	0,3850	0,3506
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (SAP)	Region 3	Vd Arm	52	29	55,77	23	44,23	4,17	2,96	NA	-	-	-	-	0,3506
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (SAP)	Region 4	SVd Arm	69	38	55,07	31	44,93	4,70	3,55	NA	1,19	0,74	1,93	0,4729	0,3506
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (SAP)	Region 4	Vd Arm	70	35	50,00	35	50,00	21,29	3,48	NA	-	-	-	-	0,3506
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	112	56	50,00	56	50,00	7,62	4,63	23,26	0,80	0,56	1,15	0,2372	0,0802
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	70	54,26	59	45,74	5,68	3,52	16,00	-	-	-	-	0,0802
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	47	60,26	31	39,74	4,67	3,48	8,08	1,36	0,86	2,15	0,1927	0,0802
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	34	50,00	34	50,00	21,29	3,48	NA	-	-	-	-	0,0802
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Race	Races other than White	SVd Arm	34	21	61,76	13	38,24	3,52	2,33	6,93	1,69	0,86	3,30	0,1231	0,1074
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Race	Races other than White	Vd Arm	40	19	47,50	21	52,50	11,27	2,89	NA	-	-	-	-	0,1074
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Race	White	SVd Arm	156	82	52,56	74	47,44	6,97	4,63	13,90	0,92	0,68	1,25	0,5954	0,1074
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Race	White	Vd Arm	157	85	54,14	72	45,86	5,68	3,71	21,29	-	-	-	-	0,1074
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	167	88	52,69	79	47,31	6,90	4,30	13,83	0,93	0,69	1,25	0,6218	NA
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	98	54,44	82	45,56	4,93	3,52	21,29	-	-	-	-	NA
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior PI therapies	N	SVd Arm	46	26	56,52	20	43,48	6,97	3,52	NA	1,00	0,57	1,78	0,9897	0,9857
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior PI therapies	N	Vd Arm	46	24	52,17	22	47,83	4,93	3,06	NA	-	-	-	-	0,9857
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior PI therapies	Y	SVd Arm	144	77	53,47	67	46,53	4,83	4,30	10,38	1,00	0,73	1,37	0,9892	0,9857
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior PI therapies	Y	Vd Arm	151	80	52,98	71	47,02	6,60	4,07	25,56	-	-	-	-	0,9857
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior anti-MM regimen	>1	SVd Arm	96	52	54,17	44	45,83	4,83	3,52	13,93	1,02	0,69	1,50	0,9372	0,9060
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior anti-MM regimen	>1	Vd Arm	101	53	52,48	48	47,52	6,70	3,48	28,55	-	-	-	-	0,9060
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior anti-MM regimen	1	SVd Arm	94	51	54,26	43	45,74	5,75	4,63	13,90	0,98	0,66	1,46	0,9298	0,9060
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior anti-MM regimen	1	Vd Arm	96	51	53,12	45	46,88	5,55	3,48	NA	-	-	-	-	0,9060
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline single cytogenetic alterations	N	SVd Arm	94	54	57,45	40	42,55	4,67	3,58	10,41	1,36	0,92	2,02	0,1205	0,0410
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline single cytogenetic alterations	N	Vd Arm	106	55	51,89	51	48,11	9,00	4,07	28,55	-	-	-	-	0,0410
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	49	51,04	47	48,96	7,62	4,30	NA	0,76	0,51	1,14	0,1772	0,0410
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Baseline single cytogenetic alterations	Y	Vd Arm	91	49	53,85	42	46,15	4,44	3,25	NA	-	-	-	-	0,0410
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior Bortezomib exposure	N	SVd Arm	58	34	58,62	24	41,38	6,93	2,33	17,28	1,09	0,66	1,80	0,7295	0,8571
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior Bortezomib exposure	N	Vd Arm	60	33	55,00	27	45,00	3,48	2,83	NA	-	-	-	-	0,8571
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior Bortezomib exposure	Y	SVd Arm	132	69	52,27	63	47,73	5,59	4,63	10,41	1,03	0,74	1,45	0,8471	0,8571
EORTC QLQ-C30 Functional Scales Emotional Functional Score	Prior Bortezomib exposure	Y	Vd Arm	137	71	51,82	66	48,18	7,98	4,44	27,43	-	-	-	-	0,8571
EORTC QLQ-C30 Functional Scales Social Functioning Score	total	-	SVd Arm	190	143	75,26	47	24,74	3,45	2,33	3,48	1,08	0,85	1,38	0,5229	NA
EORTC QLQ-C30 Functional Scales Social Functioning Score	total	-	Vd Arm	196	128	65,31	68	34,69	2,79	2,10	3,52	-	-	-	-	NA
EORTC QLQ-C30 Functional Scales Social Functioning Score	Gender	Female	SVd Arm	78	60	76,92	18	23,08	3,48	2,40	4,63	1,07	0,72	1,57	0,7482	0,7577
EORTC QLQ-C30 Functional Scales Social Functioning Score	Gender	Female	Vd Arm	85	56	65,88	29	34,12	2,37	1,74	4,27	-	-	-	-	0,7577
EORTC QLQ-C30 Functional Scales Social Functioning Score	Gender	Male	SVd Arm	112	83	74,11	29	25,89	2,40	2,33	3,48	1,15	0,83	1,60	0,3879	0,7577

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Social Functioning Score	Gender	Male	Vd Arm	111	72	64,86	39	35,14	2,79	2,10	4,17	-	-	-	-	0,7577
EORTC QLQ-C30 Functional Scales Social Functioning Score	Age Group	<65	SVd Arm	84	66	78,57	18	21,43	3,48	2,33	3,52	1,06	0,72	1,57	0,7645	0,8711
EORTC QLQ-C30 Functional Scales Social Functioning Score	Age Group	<65	Vd Arm	74	48	64,86	26	35,14	2,07	1,41	4,17	-	-	-	-	0,8711
EORTC QLQ-C30 Functional Scales Social Functioning Score	Age Group	>=65	SVd Arm	106	77	72,64	29	27,36	2,56	2,33	4,63	1,11	0,80	1,52	0,5333	0,8711
EORTC QLQ-C30 Functional Scales Social Functioning Score	Age Group	>=65	Vd Arm	122	80	65,57	42	34,43	3,02	2,30	4,27	-	-	-	-	0,8711
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline R-ISS stage	Stage I or II	SVd Arm	169	128	75,74	41	24,26	3,48	2,33	3,52	1,10	0,85	1,42	0,4848	0,5024
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline R-ISS stage	Stage I or II	Vd Arm	167	108	64,67	59	35,33	2,79	2,10	4,17	-	-	-	-	0,5024
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline R-ISS stage	Stage III	SVd Arm	12	10	83,33	2	16,67	1,33	1,18	NA	1,61	0,54	4,82	0,3915	0,5024
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline R-ISS stage	Stage III	Vd Arm	15	9	60,00	6	40,00	6,70	1,45	NA	-	-	-	-	0,5024
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline ISS stage	Stage I or II	SVd Arm	158	119	75,32	39	24,68	3,45	2,33	3,48	1,07	0,82	1,39	0,6271	0,6710
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline ISS stage	Stage I or II	Vd Arm	166	108	65,06	58	34,94	2,79	1,77	3,52	-	-	-	-	0,6710
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline ISS stage	Stage III	SVd Arm	32	24	75,00	8	25,00	2,37	1,41	7,10	0,92	0,50	1,71	0,7995	0,6710
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline ISS stage	Stage III	Vd Arm	30	20	66,67	10	33,33	2,79	2,07	NA	-	-	-	-	0,6710
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (SAP)	Region 1	SVd Arm	18	12	66,67	6	33,33	2,56	1,41	NA	0,92	0,36	2,39	0,8689	0,9015
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (SAP)	Region 1	Vd Arm	17	13	76,47	4	23,53	2,07	1,41	NA	-	-	-	-	0,9015
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (SAP)	Region 2	SVd Arm	58	46	79,31	12	20,69	2,40	2,30	3,94	0,96	0,62	1,49	0,8582	0,9015
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (SAP)	Region 2	Vd Arm	58	39	67,24	19	32,76	1,45	1,41	3,02	-	-	-	-	0,9015
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (SAP)	Region 3	SVd Arm	45	36	80,00	9	20,00	3,45	2,33	4,70	1,10	0,66	1,83	0,7228	0,9015
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (SAP)	Region 3	Vd Arm	51	34	66,67	17	33,33	3,48	2,10	5,55	-	-	-	-	0,9015
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (SAP)	Region 4	SVd Arm	69	49	71,01	20	28,99	3,48	2,33	6,47	1,19	0,78	1,81	0,4155	0,9015
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (SAP)	Region 4	Vd Arm	70	42	60,00	28	40,00	4,17	2,79	13,60	-	-	-	-	0,9015
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	112	83	74,11	29	25,89	3,48	2,33	3,98	0,97	0,71	1,33	0,8373	0,2968
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	128	84	65,62	44	34,38	2,79	1,61	3,94	-	-	-	-	0,2968
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	60	76,92	18	23,08	2,63	2,33	4,63	1,27	0,85	1,89	0,2412	0,2968
EORTC QLQ-C30 Functional Scales Social Functioning Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	44	64,71	24	35,29	3,48	2,10	6,70	-	-	-	-	0,2968
EORTC QLQ-C30 Functional Scales Social Functioning Score	Race	Races other than White	SVd Arm	34	24	70,59	10	29,41	3,48	2,33	6,18	0,78	0,44	1,40	0,4078	0,2437
EORTC QLQ-C30 Functional Scales Social Functioning Score	Race	Races other than White	Vd Arm	40	27	67,50	13	32,50	2,07	1,41	4,17	-	-	-	-	0,2437
EORTC QLQ-C30 Functional Scales Social Functioning Score	Race	White	SVd Arm	156	119	76,28	37	23,72	2,56	2,33	3,48	1,15	0,87	1,51	0,3262	0,2437
EORTC QLQ-C30 Functional Scales Social Functioning Score	Race	White	Vd Arm	156	101	64,74	55	35,26	3,02	2,10	4,17	-	-	-	-	0,2437
EORTC QLQ-C30 Functional Scales Social Functioning Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	4	80,00	1	20,00	4,63	1,18	NA	0,99	0,16	6,12	0,9876	0,8336

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Social Functioning Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	4	80,00	1	20,00	1,45	0,72	NA	-	-	-	-	0,8336
EORTC QLQ-C30 Functional Scales Social Functioning Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	167	127	76,05	40	23,95	2,56	2,33	3,48	1,20	0,93	1,55	0,1629	0,8336
EORTC QLQ-C30 Functional Scales Social Functioning Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	179	114	63,69	65	36,31	3,02	2,10	4,17	-	-	-	-	0,8336
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior PI therapies	N	SVd Arm	46	33	71,74	13	28,26	3,48	2,33	8,08	1,03	0,62	1,69	0,9204	0,8092
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior PI therapies	N	Vd Arm	46	31	67,39	15	32,61	2,79	1,45	5,16	-	-	-	-	0,8092
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior PI therapies	Y	SVd Arm	144	110	76,39	34	23,61	2,56	2,33	3,48	1,10	0,83	1,45	0,4994	0,8092
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior PI therapies	Y	Vd Arm	150	97	64,67	53	35,33	2,79	2,07	4,17	-	-	-	-	0,8092
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior anti-MM regimen	>1	SVd Arm	96	70	72,92	26	27,08	2,56	2,33	3,48	1,09	0,77	1,54	0,6194	0,9491
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior anti-MM regimen	>1	Vd Arm	101	66	65,35	35	34,65	2,79	2,10	4,86	-	-	-	-	0,9491
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior anti-MM regimen	1	SVd Arm	94	73	77,66	21	22,34	3,48	2,33	4,63	1,07	0,76	1,51	0,6841	0,9491
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior anti-MM regimen	1	Vd Arm	95	62	65,26	33	34,74	2,79	1,61	4,17	-	-	-	-	0,9491
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline single cytogenetic alterations	N	SVd Arm	94	71	75,53	23	24,47	3,48	2,33	4,63	1,13	0,81	1,59	0,4723	0,7655
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline single cytogenetic alterations	N	Vd Arm	105	69	65,71	36	34,29	3,19	2,10	4,86	-	-	-	-	0,7655
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	72	75,00	24	25,00	2,56	2,33	3,48	1,05	0,74	1,50	0,7863	0,7655
EORTC QLQ-C30 Functional Scales Social Functioning Score	Baseline single cytogenetic alterations	Y	Vd Arm	91	59	64,84	32	35,16	2,79	1,48	4,17	-	-	-	-	0,7655
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior Bortezomib exposure	N	SVd Arm	58	43	74,14	15	25,86	3,48	2,33	4,63	1,09	0,70	1,69	0,7128	0,9887
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior Bortezomib exposure	N	Vd Arm	60	40	66,67	20	33,33	2,76	1,41	4,17	-	-	-	-	0,9887
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior Bortezomib exposure	Y	SVd Arm	132	100	75,76	32	24,24	2,63	2,33	3,94	1,08	0,81	1,45	0,5935	0,9887
EORTC QLQ-C30 Functional Scales Social Functioning Score	Prior Bortezomib exposure	Y	Vd Arm	136	88	64,71	48	35,29	2,79	2,07	4,17	-	-	-	-	0,9887
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	total	-	SVd Arm	190	124	65,26	66	34,74	3,94	3,48	5,75	1,13	0,87	1,47	0,3414	NA
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	total	-	Vd Arm	196	115	58,67	81	41,33	4,17	3,45	7,85	-	-	-	-	NA
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Gender	Female	SVd Arm	78	59	75,64	19	24,36	3,48	2,56	5,75	1,50	1,00	2,26	0,0500	0,1127
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Gender	Female	Vd Arm	85	48	56,47	37	43,53	5,16	3,48	11,27	-	-	-	-	0,1127
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Gender	Male	SVd Arm	112	65	58,04	47	41,96	4,30	3,48	7,23	0,97	0,68	1,38	0,8655	0,1127
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Gender	Male	Vd Arm	111	67	60,36	44	39,64	3,71	2,79	10,12	-	-	-	-	0,1127
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Age Group	<65	SVd Arm	84	54	64,29	30	35,71	4,30	2,66	7,10	1,41	0,91	2,19	0,1231	0,2454
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Age Group	<65	Vd Arm	74	36	48,65	38	51,35	10,12	4,50	NA	-	-	-	-	0,2454

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Age Group	>=65	SVd Arm	106	70	66,04	36	33,96	3,71	3,48	6,01	1,02	0,73	1,42	0,9159	0,2454
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Age Group	>=65	Vd Arm	122	79	64,75	43	35,25	3,61	2,79	5,68	-	-	-	-	0,2454
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline R-ISS stage	Stage I or II	SVd Arm	169	111	65,68	58	34,32	3,94	3,48	6,01	1,03	0,79	1,36	0,8054	0,1665
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline R-ISS stage	Stage I or II	Vd Arm	167	103	61,68	64	38,32	3,94	3,25	6,70	-	-	-	-	0,1665
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline R-ISS stage	Stage III	SVd Arm	12	10	83,33	2	16,67	2,96	1,18	NA	2,37	0,76	7,46	0,1308	0,1665
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline R-ISS stage	Stage III	Vd Arm	15	7	46,67	8	53,33	29,70	2,37	NA	-	-	-	-	0,1665
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline ISS stage	Stage I or II	SVd Arm	158	101	63,92	57	36,08	4,30	3,48	6,01	1,09	0,82	1,44	0,5537	0,3058
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline ISS stage	Stage I or II	Vd Arm	166	98	59,04	68	40,96	4,14	3,25	7,85	-	-	-	-	0,3058
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline ISS stage	Stage III	SVd Arm	32	23	71,88	9	28,12	3,52	2,33	7,10	1,60	0,81	3,17	0,1724	0,3058
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline ISS stage	Stage III	Vd Arm	30	17	56,67	13	43,33	6,70	2,37	NA	-	-	-	-	0,3058
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (SAP)	Region 1	SVd Arm	18	11	61,11	7	38,89	2,56	1,18	NA	0,79	0,31	2,05	0,6305	0,2433
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (SAP)	Region 1	Vd Arm	17	12	70,59	5	29,41	3,06	2,10	NA	-	-	-	-	0,2433
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (SAP)	Region 2	SVd Arm	58	41	70,69	17	29,31	2,66	2,33	3,48	1,06	0,67	1,67	0,8069	0,2433
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (SAP)	Region 2	Vd Arm	58	39	67,24	19	32,76	2,79	1,87	5,09	-	-	-	-	0,2433
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (SAP)	Region 3	SVd Arm	45	28	62,22	17	37,78	6,01	4,63	11,53	0,76	0,43	1,33	0,3319	0,2433
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (SAP)	Region 3	Vd Arm	51	30	58,82	21	41,18	4,17	2,79	16,23	-	-	-	-	0,2433
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (SAP)	Region 4	SVd Arm	69	44	63,77	25	36,23	4,63	2,76	14,98	1,55	0,96	2,49	0,0680	0,2433
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (SAP)	Region 4	Vd Arm	70	34	48,57	36	51,43	14,78	5,16	NA	-	-	-	-	0,2433
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	112	71	63,39	41	36,61	4,63	3,48	6,93	0,99	0,71	1,39	0,9552	0,2010
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	128	78	60,94	50	39,06	3,94	2,79	6,70	-	-	-	-	0,2010
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	53	67,95	25	32,05	3,48	2,60	5,75	1,42	0,91	2,22	0,1164	0,2010
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	37	54,41	31	45,59	6,70	3,45	NA	-	-	-	-	0,2010

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Race	Races other than White	SVd Arm	34	22	64,71	12	35,29	3,48	2,40	NA	1,09	0,58	2,04	0,7824	0,9289
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Race	Races other than White	Vd Arm	40	22	55,00	18	45,00	6,70	1,41	NA	-	-	-	-	0,9289
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Race	White	SVd Arm	156	102	65,38	54	34,62	4,63	3,48	6,01	1,13	0,84	1,51	0,4199	0,9289
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Race	White	Vd Arm	156	93	59,62	63	40,38	4,17	3,45	7,85	-	-	-	-	0,9289
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	3	60,00	2	40,00	4,06	3,48	NA	0,97	0,09	10,98	0,9835	0,9202
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	6,70	3,45	NA	-	-	-	-	0,9202
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	167	108	64,67	59	35,33	3,71	3,48	5,85	1,10	0,84	1,45	0,4816	0,9202
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	179	106	59,22	73	40,78	4,40	3,25	8,08	-	-	-	-	0,9202
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior PI therapies	N	SVd Arm	46	28	60,87	18	39,13	4,63	3,48	17,28	1,11	0,64	1,92	0,7088	0,9275
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior PI therapies	N	Vd Arm	46	28	60,87	18	39,13	5,16	3,25	NA	-	-	-	-	0,9275
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior PI therapies	Y	SVd Arm	144	96	66,67	48	33,33	3,58	2,76	5,59	1,14	0,85	1,54	0,3790	0,9275
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior PI therapies	Y	Vd Arm	150	87	58,00	63	42,00	4,17	2,79	8,54	-	-	-	-	0,9275
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior anti-MM regimen	>1	SVd Arm	96	64	66,67	32	33,33	3,48	2,40	4,83	1,31	0,90	1,89	0,1571	0,2947
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior anti-MM regimen	>1	Vd Arm	100	56	56,00	44	44,00	6,70	2,79	14,78	-	-	-	-	0,2947
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior anti-MM regimen	1	SVd Arm	94	60	63,83	34	36,17	4,63	3,48	7,10	0,99	0,69	1,43	0,9506	0,2947
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior anti-MM regimen	1	Vd Arm	96	59	61,46	37	38,54	4,17	3,45	8,08	-	-	-	-	0,2947
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline single cytogenetic alterations	N	SVd Arm	94	62	65,96	32	34,04	3,58	2,63	6,01	1,32	0,91	1,92	0,1402	0,2685
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline single cytogenetic alterations	N	Vd Arm	106	61	57,55	45	42,45	5,09	3,19	16,23	-	-	-	-	0,2685
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	62	64,58	34	35,42	4,30	3,48	6,93	0,98	0,67	1,43	0,9173	0,2685
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Baseline single cytogenetic alterations	Y	Vd Arm	90	54	60,00	36	40,00	3,71	2,79	10,12	-	-	-	-	0,2685
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior Bortezomib exposure	N	SVd Arm	58	37	63,79	21	36,21	3,48	2,33	11,50	1,19	0,73	1,93	0,4855	0,8455
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior Bortezomib exposure	N	Vd Arm	60	37	61,67	23	38,33	3,94	3,06	10,15	-	-	-	-	0,8455

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior Bortezomib exposure	Y	SVd Arm	132	87	65,91	45	34,09	4,30	3,48	5,78	1,12	0,82	1,53	0,4718	0,8455
EORTC QLQ-C30 Functional Scales Cognitive Functioning Score	Prior Bortezomib exposure	Y	Vd Arm	136	78	57,35	58	42,65	4,50	3,45	10,12	-	-	-	-	0,8455
EORTC QLQ-C30 Global Health Status QoL Score	total	-	SVd Arm	190	125	65,79	65	34,21	4,30	3,52	5,78	1,04	0,80	1,35	0,7629	NA
EORTC QLQ-C30 Global Health Status QoL Score	total	-	Vd Arm	197	114	57,87	83	42,13	3,06	2,76	7,92	-	-	-	-	NA
EORTC QLQ-C30 Global Health Status QoL Score	Gender	Female	SVd Arm	78	57	73,08	21	26,92	3,71	2,40	5,82	1,29	0,85	1,94	0,2282	0,1316
EORTC QLQ-C30 Global Health Status QoL Score	Gender	Female	Vd Arm	86	46	53,49	40	46,51	5,16	2,79	NA	-	-	-	-	0,1316
EORTC QLQ-C30 Global Health Status QoL Score	Gender	Male	SVd Arm	112	68	60,71	44	39,29	4,63	3,55	7,62	0,85	0,60	1,21	0,3604	0,1316
EORTC QLQ-C30 Global Health Status QoL Score	Gender	Male	Vd Arm	111	68	61,26	43	38,74	2,79	2,17	6,60	-	-	-	-	0,1316
EORTC QLQ-C30 Global Health Status QoL Score	Age Group	<65	SVd Arm	84	59	70,24	25	29,76	4,30	3,52	6,24	1,22	0,80	1,86	0,3551	0,3835
EORTC QLQ-C30 Global Health Status QoL Score	Age Group	<65	Vd Arm	74	39	52,70	35	47,30	4,17	2,17	NA	-	-	-	-	0,3835
EORTC QLQ-C30 Global Health Status QoL Score	Age Group	>=65	SVd Arm	106	66	62,26	40	37,74	4,63	3,48	9,46	0,96	0,68	1,35	0,8098	0,3835
EORTC QLQ-C30 Global Health Status QoL Score	Age Group	>=65	Vd Arm	123	75	60,98	48	39,02	2,79	2,37	7,92	-	-	-	-	0,3835
EORTC QLQ-C30 Global Health Status QoL Score	Baseline R-ISS stage	Stage I or II	SVd Arm	169	116	68,64	53	31,36	3,71	3,48	5,78	1,09	0,83	1,43	0,5371	0,4070
EORTC QLQ-C30 Global Health Status QoL Score	Baseline R-ISS stage	Stage I or II	Vd Arm	168	99	58,93	69	41,07	3,06	2,76	8,61	-	-	-	-	0,4070
EORTC QLQ-C30 Global Health Status QoL Score	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	5,95	4,24	NA	0,61	0,16	2,33	0,4695	0,4070
EORTC QLQ-C30 Global Health Status QoL Score	Baseline R-ISS stage	Stage III	Vd Arm	15	6	40,00	9	60,00	NA	2,79	NA	-	-	-	-	0,4070
EORTC QLQ-C30 Global Health Status QoL Score	Baseline ISS stage	Stage I or II	SVd Arm	158	107	67,72	51	32,28	4,30	3,48	5,78	1,06	0,80	1,40	0,6655	0,8373
EORTC QLQ-C30 Global Health Status QoL Score	Baseline ISS stage	Stage I or II	Vd Arm	167	98	58,68	69	41,32	2,89	2,66	7,92	-	-	-	-	0,8373
EORTC QLQ-C30 Global Health Status QoL Score	Baseline ISS stage	Stage III	SVd Arm	32	18	56,25	14	43,75	5,75	3,55	NA	0,98	0,49	1,98	0,9603	0,8373
EORTC QLQ-C30 Global Health Status QoL Score	Baseline ISS stage	Stage III	Vd Arm	30	16	53,33	14	46,67	4,50	2,37	NA	-	-	-	-	0,8373
EORTC QLQ-C30 Global Health Status QoL Score	Region (SAP)	Region 1	SVd Arm	18	11	61,11	7	38,89	3,68	2,56	NA	0,76	0,29	1,95	0,5627	0,6998
EORTC QLQ-C30 Global Health Status QoL Score	Region (SAP)	Region 1	Vd Arm	17	10	58,82	7	41,18	2,79	2,20	NA	-	-	-	-	0,6998
EORTC QLQ-C30 Global Health Status QoL Score	Region (SAP)	Region 2	SVd Arm	58	37	63,79	21	36,21	3,58	3,45	5,82	0,84	0,52	1,34	0,4567	0,6998
EORTC QLQ-C30 Global Health Status QoL Score	Region (SAP)	Region 2	Vd Arm	58	36	62,07	22	37,93	2,79	1,68	10,12	-	-	-	-	0,6998
EORTC QLQ-C30 Global Health Status QoL Score	Region (SAP)	Region 3	SVd Arm	45	32	71,11	13	28,89	6,01	3,48	11,53	1,12	0,65	1,92	0,6788	0,6998
EORTC QLQ-C30 Global Health Status QoL Score	Region (SAP)	Region 3	Vd Arm	52	29	55,77	23	44,23	4,17	2,76	NA	-	-	-	-	0,6998
EORTC QLQ-C30 Global Health Status QoL Score	Region (SAP)	Region 4	SVd Arm	69	45	65,22	24	34,78	4,67	2,40	10,38	1,15	0,74	1,78	0,5441	0,6998
EORTC QLQ-C30 Global Health Status QoL Score	Region (SAP)	Region 4	Vd Arm	70	39	55,71	31	44,29	3,19	2,20	NA	-	-	-	-	0,6998
EORTC QLQ-C30 Global Health Status QoL Score	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	112	71	63,39	41	36,61	4,63	3,71	7,62	0,98	0,70	1,38	0,9211	0,5732

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
EORTC QLQ-C30 Global Health Status QoL Score	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	129	74	57,36	55	42,64	3,52	2,76	11,27	-	-	-	-	0,5732
EORTC QLQ-C30 Global Health Status QoL Score	Region (by medical care situation)	Rest of the world	SVd Arm	78	54	69,23	24	30,77	3,48	2,33	6,24	1,15	0,75	1,75	0,5186	0,5732
EORTC QLQ-C30 Global Health Status QoL Score	Region (by medical care situation)	Rest of the world	Vd Arm	68	40	58,82	28	41,18	2,79	2,10	NA	-	-	-	-	0,5732
EORTC QLQ-C30 Global Health Status QoL Score	Race	Races other than White	SVd Arm	34	22	64,71	12	35,29	3,68	2,40	NA	0,93	0,50	1,75	0,8318	0,8057
EORTC QLQ-C30 Global Health Status QoL Score	Race	Races other than White	Vd Arm	40	23	57,50	17	42,50	3,06	2,17	NA	-	-	-	-	0,8057
EORTC QLQ-C30 Global Health Status QoL Score	Race	White	SVd Arm	156	103	66,03	53	33,97	4,63	3,48	6,24	1,02	0,76	1,36	0,8990	0,8057
EORTC QLQ-C30 Global Health Status QoL Score	Race	White	Vd Arm	157	91	57,96	66	42,04	3,19	2,37	8,61	-	-	-	-	0,8057
EORTC QLQ-C30 Global Health Status QoL Score	Ethnicity	HISPANIC OR LATINO	SVd Arm	5	2	40,00	3	60,00	5,78	4,63	NA	1,26	0,11	14,57	0,8554	0,9284
EORTC QLQ-C30 Global Health Status QoL Score	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	4	80,00	1	20,00	2,79	1,38	NA	-	-	-	-	0,9284
EORTC QLQ-C30 Global Health Status QoL Score	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	167	110	65,87	57	34,13	3,94	3,48	5,82	1,12	0,85	1,48	0,4153	0,9284
EORTC QLQ-C30 Global Health Status QoL Score	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	180	102	56,67	78	43,33	3,25	2,76	10,12	-	-	-	-	0,9284
EORTC QLQ-C30 Global Health Status QoL Score	Prior PI therapies	N	SVd Arm	46	30	65,22	16	34,78	4,67	2,56	14,06	0,83	0,50	1,39	0,4808	0,3229
EORTC QLQ-C30 Global Health Status QoL Score	Prior PI therapies	N	Vd Arm	46	30	65,22	16	34,78	2,79	2,10	NA	-	-	-	-	0,3229
EORTC QLQ-C30 Global Health Status QoL Score	Prior PI therapies	Y	SVd Arm	144	95	65,97	49	34,03	4,24	3,48	5,78	1,12	0,83	1,52	0,4496	0,3229
EORTC QLQ-C30 Global Health Status QoL Score	Prior PI therapies	Y	Vd Arm	151	84	55,63	67	44,37	3,48	2,76	11,27	-	-	-	-	0,3229
EORTC QLQ-C30 Global Health Status QoL Score	Prior anti-MM regimen	>1	SVd Arm	96	64	66,67	32	33,33	3,71	2,66	6,24	1,23	0,85	1,78	0,2678	0,2065
EORTC QLQ-C30 Global Health Status QoL Score	Prior anti-MM regimen	>1	Vd Arm	101	57	56,44	44	43,56	4,11	2,79	16,23	-	-	-	-	0,2065
EORTC QLQ-C30 Global Health Status QoL Score	Prior anti-MM regimen	1	SVd Arm	94	61	64,89	33	35,11	4,63	3,52	7,62	0,88	0,61	1,27	0,4974	0,2065
EORTC QLQ-C30 Global Health Status QoL Score	Prior anti-MM regimen	1	Vd Arm	96	57	59,38	39	40,62	2,79	2,10	5,16	-	-	-	-	0,2065
EORTC QLQ-C30 Global Health Status QoL Score	Baseline single cytogenetic alterations	N	SVd Arm	94	62	65,96	32	34,04	4,63	3,48	7,62	1,04	0,72	1,51	0,8237	0,7952
EORTC QLQ-C30 Global Health Status QoL Score	Baseline single cytogenetic alterations	N	Vd Arm	106	59	55,66	47	44,34	3,19	2,76	NA	-	-	-	-	0,7952
EORTC QLQ-C30 Global Health Status QoL Score	Baseline single cytogenetic alterations	Y	SVd Arm	96	63	65,62	33	34,38	4,30	3,48	6,01	0,97	0,67	1,41	0,8853	0,7952
EORTC QLQ-C30 Global Health Status QoL Score	Baseline single cytogenetic alterations	Y	Vd Arm	91	55	60,44	36	39,56	2,79	2,10	10,12	-	-	-	-	0,7952
EORTC QLQ-C30 Global Health Status QoL Score	Prior Bortezomib exposure	N	SVd Arm	58	36	62,07	22	37,93	4,67	2,33	11,60	0,81	0,51	1,30	0,3818	0,2288
EORTC QLQ-C30 Global Health Status QoL Score	Prior Bortezomib exposure	N	Vd Arm	60	38	63,33	22	36,67	2,76	2,10	NA	-	-	-	-	0,2288
EORTC QLQ-C30 Global Health Status QoL Score	Prior Bortezomib exposure	Y	SVd Arm	132	89	67,42	43	32,58	4,24	3,48	5,78	1,15	0,84	1,57	0,3902	0,2288
EORTC QLQ-C30 Global Health Status QoL Score	Prior Bortezomib exposure	Y	Vd Arm	137	76	55,47	61	44,53	4,11	2,79	11,27	-	-	-	-	0,2288

2.2 Subgruppenanalysen der Sicherheitsendpunkte UE, AESI und UE nach SOC und PT

Tabelle 5: Vollständige Darstellung der Subgruppenanalysen zu UE unabhängig vom Schweregrad, schwere UE, SUE und Behandlungsabbrüche durch UE

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	total	-	SVd Arm	195	194	99,49	1	0,51	0,10	0,10	0,20	1,57	1,28	1,93	0,0000	NA
Patients with at least one AE	total	-	Vd Arm	204	198	97,06	6	2,94	0,41	0,30	0,69	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	80	80	100,00	0	0,00	0,10	0,07	0,16	1,77	1,27	2,45	0,0006	0,4112
Patients with at least one AE	Gender	Female	Vd Arm	91	87	95,60	4	4,40	0,46	0,30	0,76	-	-	-	-	0,4112
Patients with at least one AE	Gender	Male	SVd Arm	115	114	99,13	1	0,87	0,13	0,10	0,26	1,47	1,11	1,96	0,0077	0,4112
Patients with at least one AE	Gender	Male	Vd Arm	113	111	98,23	2	1,77	0,39	0,26	0,69	-	-	-	-	0,4112
Patients with at least one AE	Age Group	<65	SVd Arm	86	86	100,00	0	0,00	0,18	0,10	0,26	1,55	1,10	2,18	0,0108	0,6955
Patients with at least one AE	Age Group	<65	Vd Arm	75	71	94,67	4	5,33	0,36	0,23	0,69	-	-	-	-	0,6955
Patients with at least one AE	Age Group	>=65	SVd Arm	109	108	99,08	1	0,92	0,10	0,07	0,16	1,69	1,29	2,22	0,0001	0,6955
Patients with at least one AE	Age Group	>=65	Vd Arm	129	127	98,45	2	1,55	0,46	0,33	0,72	-	-	-	-	0,6955
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	173	172	99,42	1	0,58	0,13	0,10	0,20	1,43	1,16	1,78	0,0010	0,3283
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	174	171	98,28	3	1,72	0,38	0,30	0,69	-	-	-	-	0,3283
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	12	12	100,00	0	0,00	0,07	0,07	NA	2,44	0,86	6,94	0,0899	0,3283
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	16	14	87,50	2	12,50	0,64	0,20	4,34	-	-	-	-	0,3283
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	163	162	99,39	1	0,61	0,10	0,10	0,20	1,59	1,27	1,98	0,0000	0,7028
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	173	169	97,69	4	2,31	0,36	0,30	0,69	-	-	-	-	0,7028
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	32	32	100,00	0	0,00	0,13	0,07	0,69	1,78	1,03	3,06	0,0354	0,7028
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	31	29	93,55	2	6,45	0,62	0,23	2,07	-	-	-	-	0,7028
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	18	18	100,00	0	0,00	0,05	0,03	0,07	2,01	0,87	4,67	0,0987	0,2222
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	17	17	100,00	0	0,00	0,26	0,10	0,43	-	-	-	-	0,2222
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	61	61	100,00	0	0,00	0,07	0,03	0,10	1,57	1,08	2,29	0,0183	0,2222
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	64	64	100,00	0	0,00	0,16	0,13	0,26	-	-	-	-	0,2222
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	47	46	97,87	1	2,13	0,43	0,26	0,72	1,21	0,78	1,87	0,3936	0,2222
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	53	51	96,23	2	3,77	0,72	0,36	1,08	-	-	-	-	0,2222
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	69	69	100,00	0	0,00	0,20	0,10	0,26	2,19	1,51	3,19	0,0000	0,2222
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	70	66	94,29	4	5,71	1,07	0,72	1,58	-	-	-	-	0,2222
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	116	99,15	1	0,85	0,10	0,07	0,26	1,35	1,04	1,75	0,0248	0,0438
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	134	98,53	2	1,47	0,33	0,26	0,53	-	-	-	-	0,0438
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	78	78	100,00	0	0,00	0,13	0,10	0,23	2,15	1,48	3,11	0,0000	0,0438
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	68	64	94,12	4	5,88	0,72	0,39	1,15	-	-	-	-	0,0438
Patients with at least one AE	Race	Races other than White	SVd Arm	34	34	100,00	0	0,00	0,13	0,10	0,26	1,68	1,01	2,80	0,0448	0,8995
Patients with at least one AE	Race	Races other than White	Vd Arm	42	42	100,00	0	0,00	0,18	0,13	0,39	-	-	-	-	0,8995
Patients with at least one AE	Race	White	SVd Arm	161	160	99,38	1	0,62	0,10	0,07	0,20	1,62	1,29	2,04	0,0000	0,8995
Patients with at least one AE	Race	White	Vd Arm	162	156	96,30	6	3,70	0,57	0,36	0,72	-	-	-	-	0,8995
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	6	100,00	0	0,00	0,05	0,03	NA	4,96	0,56	43,77	0,1126	0,2871
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	4	80,00	1	20,00	0,46	0,36	NA	-	-	-	-	0,2871

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	170	99,42	1	0,58	0,10	0,10	0,20	1,51	1,22	1,88	0,0002	0,2871
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	180	97,30	5	2,70	0,39	0,30	0,69	-	-	-	-	0,2871
Patients with at least one AE	Prior PI therapies	N	SVd Arm	48	47	97,92	1	2,08	0,10	0,07	0,26	1,76	1,14	2,72	0,0101	0,5600
Patients with at least one AE	Prior PI therapies	N	Vd Arm	47	45	95,74	2	4,26	0,72	0,26	1,41	-	-	-	-	0,5600
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	147	147	100,00	0	0,00	0,13	0,07	0,20	1,52	1,20	1,92	0,0004	0,5600
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	157	153	97,45	4	2,55	0,36	0,30	0,62	-	-	-	-	0,5600
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	98	98	100,00	0	0,00	0,13	0,07	0,20	1,76	1,31	2,36	0,0001	0,2780
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	104	100	96,15	4	3,85	0,53	0,26	0,72	-	-	-	-	0,2780
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	97	96	98,97	1	1,03	0,10	0,10	0,26	1,40	1,05	1,87	0,0219	0,2780
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	100	98	98,00	2	2,00	0,39	0,26	0,69	-	-	-	-	0,2780
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	98	97	98,98	1	1,02	0,16	0,10	0,26	1,48	1,10	1,97	0,0082	0,5865
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	111	109	98,20	2	1,80	0,46	0,30	0,72	-	-	-	-	0,5865
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	97	97	100,00	0	0,00	0,10	0,07	0,16	1,66	1,22	2,25	0,0010	0,5865
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	93	89	95,70	4	4,30	0,39	0,26	0,72	-	-	-	-	0,5865
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	61	60	98,36	1	1,64	0,10	0,07	0,26	1,75	1,18	2,60	0,0050	0,5448
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	62	60	96,77	2	3,23	0,72	0,26	1,05	-	-	-	-	0,5448
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	134	134	100,00	0	0,00	0,13	0,07	0,23	1,52	1,18	1,94	0,0009	0,5448
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	142	138	97,18	4	2,82	0,36	0,30	0,66	-	-	-	-	0,5448
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	195	169	86,67	26	13,33	1,71	1,41	2,33	1,72	1,36	2,17	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	204	128	62,75	76	37,25	3,25	2,43	5,59	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	80	69	86,25	11	13,75	1,64	1,41	2,33	2,03	1,38	2,98	0,0003	0,4496
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	91	60	65,93	31	34,07	3,22	2,10	6,47	-	-	-	-	0,4496
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	115	100	86,96	15	13,04	2,10	1,35	3,15	1,67	1,22	2,30	0,0013	0,4496
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	113	68	60,18	45	39,82	3,25	2,14	7,13	-	-	-	-	0,4496
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	86	77	89,53	9	10,47	2,10	1,41	3,98	2,09	1,40	3,12	0,0002	0,3948
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	75	39	52,00	36	48,00	5,88	2,37	NA	-	-	-	-	0,3948
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	109	92	84,40	17	15,60	1,54	1,18	2,33	1,68	1,24	2,27	0,0008	0,3948
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	129	89	68,99	40	31,01	3,06	2,10	5,16	-	-	-	-	0,3948
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	173	148	85,55	25	14,45	1,87	1,41	2,46	1,62	1,26	2,08	0,0001	0,5144
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	174	112	64,37	62	35,63	3,29	2,60	5,59	-	-	-	-	0,5144
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	12	12	100,00	0	0,00	1,07	0,26	NA	2,27	0,85	6,05	0,0961	0,5144
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	16	9	56,25	7	43,75	2,10	0,62	NA	-	-	-	-	0,5144

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	163	140	85,89	23	14,11	1,64	1,41	2,46	1,78	1,38	2,29	0,0000	0,4083
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	173	107	61,85	66	38,15	3,58	2,76	6,44	-	-	-	-	0,4083
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	32	29	90,62	3	9,38	2,02	0,82	3,06	1,36	0,76	2,43	0,2933	0,4083
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	31	21	67,74	10	32,26	2,10	0,72	NA	-	-	-	-	0,4083
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	18	16	88,89	2	11,11	1,17	0,72	NA	2,60	0,91	7,45	0,0659	0,6959
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	17	9	52,94	8	47,06	10,12	1,38	NA	-	-	-	-	0,6959
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	61	55	90,16	6	9,84	1,18	0,92	1,74	1,55	1,03	2,32	0,0337	0,6959
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	64	44	68,75	20	31,25	2,60	1,68	4,14	-	-	-	-	0,6959
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	47	38	80,85	9	19,15	3,25	1,87	5,39	1,33	0,79	2,24	0,2776	0,6959
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	53	31	58,49	22	41,51	2,96	1,51	NA	-	-	-	-	0,6959
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	69	60	86,96	9	13,04	2,10	1,38	3,29	1,72	1,15	2,56	0,0073	0,6959
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	70	44	62,86	26	37,14	5,59	2,76	17,02	-	-	-	-	0,6959
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	98	83,76	19	16,24	1,87	1,41	2,79	1,57	1,16	2,12	0,0034	0,5690
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	84	61,76	52	38,24	3,02	2,10	6,24	-	-	-	-	0,5690
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	78	71	91,03	7	8,97	1,66	1,35	2,37	1,81	1,23	2,66	0,0022	0,5690
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	68	44	64,71	24	35,29	5,16	2,37	13,21	-	-	-	-	0,5690
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	34	29	85,29	5	14,71	2,63	1,28	4,17	1,51	0,85	2,67	0,1565	0,6276
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	42	27	64,29	15	35,71	2,60	1,74	NA	-	-	-	-	0,6276
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	161	140	86,96	21	13,04	1,64	1,38	2,33	1,76	1,35	2,30	0,0000	0,6276
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	162	101	62,35	61	37,65	3,35	2,63	6,44	-	-	-	-	0,6276
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	6	100,00	0	0,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	148	86,55	23	13,45	1,68	1,38	2,56	1,70	1,32	2,18	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	117	63,24	68	36,76	3,22	2,37	5,59	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	48	40	83,33	8	16,67	2,46	1,68	5,68	1,43	0,88	2,33	0,1437	0,4050
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	47	32	68,09	15	31,91	5,29	2,43	13,21	-	-	-	-	0,4050
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	147	129	87,76	18	12,24	1,41	1,35	2,14	1,81	1,39	2,37	0,0000	0,4050
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	157	96	61,15	61	38,85	3,02	2,10	5,59	-	-	-	-	0,4050
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	98	87	88,78	11	11,22	1,41	1,25	2,33	2,03	1,45	2,83	0,0000	0,1632

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	104	63	60,58	41	39,42	3,58	2,43	8,18	-	-	-	-	0,1632
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	97	82	84,54	15	15,46	2,10	1,54	3,48	1,45	1,04	2,02	0,0270	0,1632
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	100	65	65,00	35	35,00	2,79	2,10	6,44	-	-	-	-	0,1632
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	98	85	86,73	13	13,27	1,74	1,35	2,79	1,57	1,13	2,18	0,0066	0,5851
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	111	68	61,26	43	38,74	3,06	2,10	6,44	-	-	-	-	0,5851
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	97	84	86,60	13	13,40	1,64	1,38	2,33	1,79	1,27	2,53	0,0008	0,5851
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	93	60	64,52	33	35,48	3,35	2,14	7,13	-	-	-	-	0,5851
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	61	52	85,25	9	14,75	2,10	1,31	3,94	1,57	1,01	2,44	0,0428	0,6556
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	62	41	66,13	21	33,87	3,71	2,10	7,23	-	-	-	-	0,6556
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	134	117	87,31	17	12,69	1,51	1,38	2,33	1,77	1,33	2,35	0,0001	0,6556
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	142	87	61,27	55	38,73	3,22	2,10	5,59	-	-	-	-	0,6556
Patients with at least one SAE	total	-	SVd Arm	195	109	55,90	86	44,10	7,98	5,68	21,26	1,50	1,11	2,01	0,0071	NA
Patients with at least one SAE	total	-	Vd Arm	204	79	38,73	125	61,27	20,90	10,48	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	80	51	63,75	29	36,25	5,72	4,53	10,05	1,91	1,20	3,04	0,0058	0,2298
Patients with at least one SAE	Gender	Female	Vd Arm	91	36	39,56	55	60,44	17,94	10,48	NA	-	-	-	-	0,2298
Patients with at least one SAE	Gender	Male	SVd Arm	115	58	50,43	57	49,57	14,03	6,87	29,31	1,31	0,87	1,96	0,1912	0,2298
Patients with at least one SAE	Gender	Male	Vd Arm	113	43	38,05	70	61,95	20,90	9,20	NA	-	-	-	-	0,2298
Patients with at least one SAE	Age Group	<65	SVd Arm	86	46	53,49	40	46,51	11,30	6,87	27,14	1,93	1,11	3,36	0,0183	0,3462
Patients with at least one SAE	Age Group	<65	Vd Arm	75	19	25,33	56	74,67	NA	17,94	NA	-	-	-	-	0,3462
Patients with at least one SAE	Age Group	>=65	SVd Arm	109	63	57,80	46	42,20	5,72	4,17	23,43	1,40	0,98	2,02	0,0648	0,3462
Patients with at least one SAE	Age Group	>=65	Vd Arm	129	60	46,51	69	53,49	11,99	5,59	NA	-	-	-	-	0,3462
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	173	100	57,80	73	42,20	7,79	5,55	14,03	1,52	1,11	2,07	0,0089	0,3134
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	174	67	38,51	107	61,49	17,94	10,48	NA	-	-	-	-	0,3134
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	5,65	3,06	NA	0,74	0,19	2,87	0,6652	0,3134
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	16	6	37,50	10	62,50	NA	2,10	NA	-	-	-	-	0,3134
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	163	90	55,21	73	44,79	8,38	5,68	21,26	1,52	1,11	2,10	0,0094	0,6098
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	173	66	38,15	107	61,85	17,94	10,48	NA	-	-	-	-	0,6098
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	32	19	59,38	13	40,62	6,87	3,78	NA	1,24	0,59	2,59	0,5741	0,6098
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	31	13	41,94	18	58,06	20,90	2,10	NA	-	-	-	-	0,6098
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	18	8	44,44	10	55,56	32,00	2,46	NA	0,99	0,26	3,77	0,9915	0,3305
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	17	5	29,41	12	70,59	NA	10,48	NA	-	-	-	-	0,3305
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	61	40	65,57	21	34,43	4,80	2,92	7,79	2,13	1,27	3,57	0,0032	0,3305
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	64	25	39,06	39	60,94	15,01	5,55	NA	-	-	-	-	0,3305
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	47	24	51,06	23	48,94	10,91	5,55	NA	1,16	0,60	2,24	0,6525	0,3305
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	53	18	33,96	35	66,04	NA	8,18	NA	-	-	-	-	0,3305
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	69	37	53,62	32	46,38	11,30	6,87	37,32	1,21	0,74	1,98	0,4426	0,3305
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	70	31	44,29	39	55,71	17,94	7,23	NA	-	-	-	-	0,3305
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	63	53,85	54	46,15	7,79	5,52	22,57	1,50	1,01	2,22	0,0411	0,7412
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	48	35,29	88	64,71	28,88	10,48	NA	-	-	-	-	0,7412

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	78	46	58,97	32	41,03	7,98	3,98	26,41	1,35	0,85	2,16	0,2025	0,7412
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	68	31	45,59	37	54,41	15,01	5,95	NA	-	-	-	-	0,7412
Patients with at least one SAE	Race	Races other than White	SVd Arm	34	23	67,65	11	32,35	4,53	2,04	10,55	2,06	1,04	4,07	0,0354	0,2650
Patients with at least one SAE	Race	Races other than White	Vd Arm	42	15	35,71	27	64,29	NA	6,24	NA	-	-	-	-	0,2650
Patients with at least one SAE	Race	White	SVd Arm	161	86	53,42	75	46,58	10,91	6,74	23,72	1,33	0,95	1,86	0,0902	0,2650
Patients with at least one SAE	Race	White	Vd Arm	162	64	39,51	98	60,49	17,94	9,20	NA	-	-	-	-	0,2650
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	5	83,33	1	16,67	5,52	4,37	NA	1,80	0,18	17,92	0,6104	0,8732
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	NA	NA	NA	-	-	-	-	0,8732
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	93	54,39	78	45,61	10,05	6,34	23,72	1,49	1,09	2,05	0,0131	0,8732
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	71	38,38	114	61,62	20,90	11,99	NA	-	-	-	-	0,8732
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	48	31	64,58	17	35,42	6,57	3,55	27,14	1,19	0,69	2,06	0,5338	0,3370
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	47	25	53,19	22	46,81	7,23	5,55	NA	-	-	-	-	0,3370
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	147	78	53,06	69	46,94	8,61	5,72	23,43	1,64	1,15	2,33	0,0053	0,3370
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	157	54	34,39	103	65,61	28,88	17,94	NA	-	-	-	-	0,3370
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	98	57	58,16	41	41,84	8,38	3,98	25,23	2,03	1,33	3,12	0,0009	0,0469
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	104	35	33,65	69	66,35	17,94	14,98	NA	-	-	-	-	0,0469
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	97	52	53,61	45	46,39	7,98	5,68	29,31	1,12	0,74	1,68	0,6002	0,0469
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	100	44	44,00	56	56,00	20,90	5,55	NA	-	-	-	-	0,0469
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	98	59	60,20	39	39,80	7,72	5,65	21,26	1,63	1,09	2,44	0,0170	0,5517
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	111	42	37,84	69	62,16	28,88	15,01	NA	-	-	-	-	0,5517
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	97	50	51,55	47	48,45	11,17	5,26	29,31	1,36	0,87	2,11	0,1747	0,5517
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	93	37	39,78	56	60,22	11,99	7,23	NA	-	-	-	-	0,5517
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	61	41	67,21	20	32,79	5,26	2,37	22,57	1,39	0,84	2,32	0,1995	0,7671
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	62	30	48,39	32	51,61	9,20	5,55	NA	-	-	-	-	0,7671
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	134	68	50,75	66	49,25	10,05	6,87	26,41	1,53	1,06	2,23	0,0235	0,7671
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	142	49	34,51	93	65,49	28,88	17,94	NA	-	-	-	-	0,7671
Patients with treatment discontinuation due to at least one AE	total	-	SVd Arm	195	42	21,54	153	78,46	NA	NA	NA	1,20	0,76	1,88	0,4387	NA
Patients with treatment discontinuation due to at least one AE	total	-	Vd Arm	204	35	17,16	169	82,84	NA	NA	NA	-	-	-	-	NA
Patients with treatment discontinuation due to at least one AE	Gender	Female	SVd Arm	80	21	26,25	59	73,75	NA	22,57	NA	1,61	0,78	3,29	0,1927	0,2997
Patients with treatment discontinuation due to at least one AE	Gender	Female	Vd Arm	91	15	16,48	76	83,52	NA	27,66	NA	-	-	-	-	0,2997
Patients with treatment discontinuation due to at least one AE	Gender	Male	SVd Arm	115	21	18,26	94	81,74	NA	NA	NA	0,97	0,52	1,80	0,9302	0,2997
Patients with treatment discontinuation due to at least one AE	Gender	Male	Vd Arm	113	20	17,70	93	82,30	NA	NA	NA	-	-	-	-	0,2997
Patients with treatment discontinuation due to at least one AE	Age Group	<65	SVd Arm	86	12	13,95	74	86,05	NA	NA	NA	1,04	0,41	2,67	0,9281	0,6487

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with treatment discontinuation due to at least one AE	Age Group	<65	Vd Arm	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,6487
Patients with treatment discontinuation due to at least one AE	Age Group	>=65	SVd Arm	109	30	27,52	79	72,48	NA	11,53	NA	1,34	0,79	2,27	0,2734	0,6487
Patients with treatment discontinuation due to at least one AE	Age Group	>=65	Vd Arm	129	27	20,93	102	79,07	NA	27,66	NA	-	-	-	-	0,6487
Patients with treatment discontinuation due to at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	173	38	21,97	135	78,03	NA	NA	NA	1,05	0,65	1,69	0,8494	0,7352
Patients with treatment discontinuation due to at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	174	32	18,39	142	81,61	NA	NA	NA	-	-	-	-	0,7352
Patients with treatment discontinuation due to at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	NA	NA	NA	1,73	0,10	30,76	0,7055	0,7352
Patients with treatment discontinuation due to at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	24,34	24,34	NA	-	-	-	-	0,7352
Patients with treatment discontinuation due to at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	163	37	22,70	126	77,30	NA	NA	NA	1,10	0,69	1,77	0,6886	0,3753
Patients with treatment discontinuation due to at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	173	33	19,08	140	80,92	NA	NA	NA	-	-	-	-	0,3753
Patients with treatment discontinuation due to at least one AE	Baseline ISS stage	Stage III	SVd Arm	32	5	15,62	27	84,38	NA	28,35	NA	2,47	0,44	13,75	0,2881	0,3753
Patients with treatment discontinuation due to at least one AE	Baseline ISS stage	Stage III	Vd Arm	31	2	6,45	29	93,55	NA	24,34	NA	-	-	-	-	0,3753
Patients with treatment discontinuation due to at least one AE	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	NA	NA	NA	0,29	0,03	2,83	0,2599	0,4031
Patients with treatment discontinuation due to at least one AE	Region (SAP)	Region 1	Vd Arm	17	3	17,65	14	82,35	NA	NA	NA	-	-	-	-	0,4031
Patients with treatment discontinuation due to at least one AE	Region (SAP)	Region 2	SVd Arm	61	20	32,79	41	67,21	NA	6,57	NA	1,53	0,78	3,02	0,2133	0,4031
Patients with treatment discontinuation due to at least one AE	Region (SAP)	Region 2	Vd Arm	64	15	23,44	49	76,56	27,66	26,38	NA	-	-	-	-	0,4031
Patients with treatment discontinuation due to at least one AE	Region (SAP)	Region 3	SVd Arm	47	11	23,40	36	76,60	NA	22,57	NA	0,76	0,31	1,89	0,5581	0,4031
Patients with treatment discontinuation due to at least one AE	Region (SAP)	Region 3	Vd Arm	53	11	20,75	42	79,25	NA	NA	NA	-	-	-	-	0,4031
Patients with treatment discontinuation due to at least one AE	Region (SAP)	Region 4	SVd Arm	69	8	11,59	61	88,41	NA	NA	NA	1,31	0,45	3,81	0,6223	0,4031
Patients with treatment discontinuation due to at least one AE	Region (SAP)	Region 4	Vd Arm	70	6	8,57	64	91,43	NA	NA	NA	-	-	-	-	0,4031
Patients with treatment discontinuation due to at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	29	24,79	88	75,21	NA	NA	NA	1,23	0,70	2,14	0,4741	0,9732
Patients with treatment discontinuation due to at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	25	18,38	111	81,62	NA	27,66	NA	-	-	-	-	0,9732
Patients with treatment discontinuation due to at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	78	13	16,67	65	83,33	NA	NA	NA	1,25	0,54	2,88	0,6050	0,9732
Patients with treatment discontinuation due to at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	68	10	14,71	58	85,29	NA	NA	NA	-	-	-	-	0,9732
Patients with treatment discontinuation due to at least one AE	Race	Races other than White	SVd Arm	34	6	17,65	28	82,35	NA	NA	NA	0,79	0,26	2,34	0,6649	0,4110
Patients with treatment discontinuation due to at least one AE	Race	Races other than White	Vd Arm	42	9	21,43	33	78,57	NA	24,34	NA	-	-	-	-	0,4110
Patients with treatment discontinuation due to at least one AE	Race	White	SVd Arm	161	36	22,36	125	77,64	NA	NA	NA	1,30	0,78	2,19	0,3131	0,4110
Patients with treatment discontinuation due to at least one AE	Race	White	Vd Arm	162	26	16,05	136	83,95	NA	NA	NA	-	-	-	-	0,4110
Patients with treatment discontinuation due to at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with treatment discontinuation due to at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with treatment discontinuation due to at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	32	18,71	139	81,29	NA	NA	NA	1,08	0,65	1,79	0,7593	NA

Endpunkt	Subgruppen-merkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with treatment discontinuation due to at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	31	16,76	154	83,24	NA	NA	NA	-	-	-	-	NA
Patients with treatment discontinuation due to at least one AE	Prior PI therapies	N	SVd Arm	48	16	33,33	32	66,67	NA	12,22	NA	1,44	0,64	3,26	0,3740	0,5825
Patients with treatment discontinuation due to at least one AE	Prior PI therapies	N	Vd Arm	47	10	21,28	37	78,72	NA	NA	NA	-	-	-	-	0,5825
Patients with treatment discontinuation due to at least one AE	Prior PI therapies	Y	SVd Arm	147	26	17,69	121	82,31	NA	NA	NA	1,10	0,63	1,90	0,7446	0,5825
Patients with treatment discontinuation due to at least one AE	Prior PI therapies	Y	Vd Arm	157	25	15,92	132	84,08	NA	NA	NA	-	-	-	-	0,5825
Patients with treatment discontinuation due to at least one AE	Prior anti-MM regimen	>1	SVd Arm	98	20	20,41	78	79,59	NA	NA	NA	1,22	0,63	2,36	0,5596	0,9439
Patients with treatment discontinuation due to at least one AE	Prior anti-MM regimen	>1	Vd Arm	104	16	15,38	88	84,62	NA	NA	NA	-	-	-	-	0,9439
Patients with treatment discontinuation due to at least one AE	Prior anti-MM regimen	1	SVd Arm	97	22	22,68	75	77,32	NA	NA	NA	1,18	0,63	2,20	0,6073	0,9439
Patients with treatment discontinuation due to at least one AE	Prior anti-MM regimen	1	Vd Arm	100	19	19,00	81	81,00	NA	26,38	NA	-	-	-	-	0,9439
Patients with treatment discontinuation due to at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	98	25	25,51	73	74,49	NA	28,35	NA	1,13	0,64	2,00	0,6719	0,8697
Patients with treatment discontinuation due to at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	111	24	21,62	87	78,38	NA	NA	NA	-	-	-	-	0,8697
Patients with treatment discontinuation due to at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	97	17	17,53	80	82,47	NA	NA	NA	1,23	0,57	2,64	0,6030	0,8697
Patients with treatment discontinuation due to at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	93	11	11,83	82	88,17	NA	27,66	NA	-	-	-	-	0,8697
Patients with treatment discontinuation due to at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	61	20	32,79	41	67,21	NA	12,22	NA	1,12	0,56	2,23	0,7474	0,8137
Patients with treatment discontinuation due to at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	62	16	25,81	46	74,19	NA	NA	NA	-	-	-	-	0,8137
Patients with treatment discontinuation due to at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	134	22	16,42	112	83,58	NA	NA	NA	1,25	0,68	2,32	0,4746	0,8137
Patients with treatment discontinuation due to at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	142	19	13,38	123	86,62	NA	NA	NA	-	-	-	-	0,8137

Tabelle 6: Vollständige Darstellung der Subgruppenanalysen zu AESI

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Thrombocytopenia	total	-	SVd Arm	195	121	62,05	74	37,95	2,79	1,61	4,86	3,03	2,19	4,18	0,0000	NA
Patients with at least one AESI or AECI Thrombocytopenia	total	-	Vd Arm	204	56	27,45	148	72,55	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Thrombocytopenia	Gender	Female	SVd Arm	80	44	55,00	36	45,00	4,17	2,10	NA	2,69	1,58	4,56	0,0002	0,3906
Patients with at least one AESI or AECI Thrombocytopenia	Gender	Female	Vd Arm	91	25	27,47	66	72,53	NA	20,47	NA	-	-	-	-	0,3906
Patients with at least one AESI or AECI Thrombocytopenia	Gender	Male	SVd Arm	115	77	66,96	38	33,04	1,68	1,41	4,17	3,62	2,36	5,56	0,0000	0,3906
Patients with at least one AESI or AECI Thrombocytopenia	Gender	Male	Vd Arm	113	31	27,43	82	72,57	NA	NA	NA	-	-	-	-	0,3906
Patients with at least one AESI or AECI Thrombocytopenia	Age Group	<65	SVd Arm	86	53	61,63	33	38,37	4,17	2,10	9,79	2,52	1,53	4,17	0,0002	0,3865
Patients with at least one AESI or AECI Thrombocytopenia	Age Group	<65	Vd Arm	75	23	30,67	52	69,33	NA	16,82	NA	-	-	-	-	0,3865
Patients with at least one AESI or AECI Thrombocytopenia	Age Group	>=65	SVd Arm	109	68	62,39	41	37,61	1,41	1,41	4,86	3,37	2,20	5,16	0,0000	0,3865
Patients with at least one AESI or AECI Thrombocytopenia	Age Group	>=65	Vd Arm	129	33	25,58	96	74,42	NA	NA	NA	-	-	-	-	0,3865
Patients with at least one AESI or AECI Thrombocytopenia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	106	61,27	67	38,73	3,32	1,64	7,43	3,05	2,16	4,33	0,0000	0,6243
Patients with at least one AESI or AECI Thrombocytopenia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	46	26,44	128	73,56	NA	NA	NA	-	-	-	-	0,6243
Patients with at least one AESI or AECI Thrombocytopenia	Baseline R-ISS stage	Stage III	SVd Arm	12	10	83,33	2	16,67	1,41	0,95	NA	2,29	0,76	6,87	0,1329	0,6243
Patients with at least one AESI or AECI Thrombocytopenia	Baseline R-ISS stage	Stage III	Vd Arm	16	7	43,75	9	56,25	10,97	0,69	NA	-	-	-	-	0,6243
Patients with at least one AESI or AECI Thrombocytopenia	Baseline ISS stage	Stage I or II	SVd Arm	163	100	61,35	63	38,65	3,71	1,61	7,59	3,11	2,18	4,44	0,0000	0,4190
Patients with at least one AESI or AECI Thrombocytopenia	Baseline ISS stage	Stage I or II	Vd Arm	173	45	26,01	128	73,99	NA	NA	NA	-	-	-	-	0,4190
Patients with at least one AESI or AECI Thrombocytopenia	Baseline ISS stage	Stage III	SVd Arm	32	21	65,62	11	34,38	2,10	1,41	NA	2,21	1,05	4,68	0,0330	0,4190
Patients with at least one AESI or AECI Thrombocytopenia	Baseline ISS stage	Stage III	Vd Arm	31	11	35,48	20	64,52	NA	10,97	NA	-	-	-	-	0,4190
Patients with at least one AESI or AECI Thrombocytopenia	Region (SAP)	Region 1	SVd Arm	18	14	77,78	4	22,22	2,89	0,69	NA	3,68	0,98	13,77	0,0404	0,6240
Patients with at least one AESI or AECI Thrombocytopenia	Region (SAP)	Region 1	Vd Arm	17	6	35,29	11	64,71	NA	1,05	NA	-	-	-	-	0,6240
Patients with at least one AESI or AECI Thrombocytopenia	Region (SAP)	Region 2	SVd Arm	61	42	68,85	19	31,15	1,41	0,85	2,83	2,30	1,38	3,83	0,0010	0,6240
Patients with at least one AESI or AECI Thrombocytopenia	Region (SAP)	Region 2	Vd Arm	64	25	39,06	39	60,94	NA	6,24	NA	-	-	-	-	0,6240
Patients with at least one AESI or AECI Thrombocytopenia	Region (SAP)	Region 3	SVd Arm	47	25	53,19	22	46,81	6,93	1,64	NA	3,75	1,73	8,11	0,0003	0,6240
Patients with at least one AESI or AECI Thrombocytopenia	Region (SAP)	Region 3	Vd Arm	53	9	16,98	44	83,02	NA	NA	NA	-	-	-	-	0,6240
Patients with at least one AESI or AECI Thrombocytopenia	Region (SAP)	Region 4	SVd Arm	69	40	57,97	29	42,03	4,17	1,81	23,26	3,54	1,96	6,39	0,0000	0,6240
Patients with at least one AESI or AECI Thrombocytopenia	Region (SAP)	Region 4	Vd Arm	70	16	22,86	54	77,14	NA	NA	NA	-	-	-	-	0,6240
Patients with at least one AESI or AECI Thrombocytopenia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	71	60,68	46	39,32	3,32	1,41	8,34	2,46	1,67	3,63	0,0000	0,0888
Patients with at least one AESI or AECI Thrombocytopenia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	42	30,88	94	69,12	NA	NA	NA	-	-	-	-	0,0888
Patients with at least one AESI or AECI Thrombocytopenia	Region (by medical care situation)	Rest of the world	SVd Arm	78	50	64,10	28	35,90	2,10	1,41	10,64	4,58	2,51	8,36	0,0000	0,0888

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Thrombocytopenia	Region (by medical care situation)	Rest of the world	Vd Arm	68	14	20,59	54	79,41	NA	NA	NA	-	-	-	-	0,0888
Patients with at least one AESI or AECI Thrombocytopenia	Race	Races other than White	SVd Arm	34	19	55,88	15	44,12	4,14	1,68	NA	3,53	1,49	8,39	0,0026	0,6163
Patients with at least one AESI or AECI Thrombocytopenia	Race	Races other than White	Vd Arm	42	9	21,43	33	78,57	NA	NA	NA	-	-	-	-	0,6163
Patients with at least one AESI or AECI Thrombocytopenia	Race	White	SVd Arm	161	102	63,35	59	36,65	2,10	1,41	4,86	2,78	1,96	3,94	0,0000	0,6163
Patients with at least one AESI or AECI Thrombocytopenia	Race	White	Vd Arm	162	47	29,01	115	70,99	NA	NA	NA	-	-	-	-	0,6163
Patients with at least one AESI or AECI Thrombocytopenia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	5	83,33	1	16,67	0,82	0,26	NA	2,88	0,32	26,18	0,3270	0,9666
Patients with at least one AESI or AECI Thrombocytopenia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	NA	1,05	NA	-	-	-	-	0,9666
Patients with at least one AESI or AECI Thrombocytopenia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	106	61,99	65	38,01	3,32	1,64	7,43	3,02	2,15	4,24	0,0000	0,9666
Patients with at least one AESI or AECI Thrombocytopenia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	51	27,57	134	72,43	NA	NA	NA	-	-	-	-	0,9666
Patients with at least one AESI or AECI Thrombocytopenia	Prior PI therapies	N	SVd Arm	48	28	58,33	20	41,67	4,17	1,64	NA	3,49	1,68	7,24	0,0004	0,6676
Patients with at least one AESI or AECI Thrombocytopenia	Prior PI therapies	N	Vd Arm	47	10	21,28	37	78,72	NA	NA	NA	-	-	-	-	0,6676
Patients with at least one AESI or AECI Thrombocytopenia	Prior PI therapies	Y	SVd Arm	147	93	63,27	54	36,73	1,81	1,41	4,27	2,92	2,04	4,18	0,0000	0,6676
Patients with at least one AESI or AECI Thrombocytopenia	Prior PI therapies	Y	Vd Arm	157	46	29,30	111	70,70	NA	NA	NA	-	-	-	-	0,6676
Patients with at least one AESI or AECI Thrombocytopenia	Prior anti-MM regimen	>1	SVd Arm	98	61	62,24	37	37,76	2,99	1,41	7,59	3,17	2,00	5,00	0,0000	0,7832
Patients with at least one AESI or AECI Thrombocytopenia	Prior anti-MM regimen	>1	Vd Arm	104	28	26,92	76	73,08	NA	NA	NA	-	-	-	-	0,7832
Patients with at least one AESI or AECI Thrombocytopenia	Prior anti-MM regimen	1	SVd Arm	97	60	61,86	37	38,14	2,79	1,41	9,99	2,89	1,84	4,55	0,0000	0,7832
Patients with at least one AESI or AECI Thrombocytopenia	Prior anti-MM regimen	1	Vd Arm	100	28	28,00	72	72,00	NA	NA	NA	-	-	-	-	0,7832
Patients with at least one AESI or AECI Thrombocytopenia	Baseline single cytogenetic alterations	N	SVd Arm	98	55	56,12	43	43,88	4,17	1,68	10,64	3,05	1,91	4,89	0,0000	0,8184
Patients with at least one AESI or AECI Thrombocytopenia	Baseline single cytogenetic alterations	N	Vd Arm	111	27	24,32	84	75,68	NA	NA	NA	-	-	-	-	0,8184
Patients with at least one AESI or AECI Thrombocytopenia	Baseline single cytogenetic alterations	Y	SVd Arm	97	66	68,04	31	31,96	1,64	1,41	4,17	2,83	1,80	4,45	0,0000	0,8184
Patients with at least one AESI or AECI Thrombocytopenia	Baseline single cytogenetic alterations	Y	Vd Arm	93	29	31,18	64	68,82	NA	NA	NA	-	-	-	-	0,8184
Patients with at least one AESI or AECI Thrombocytopenia	Previously Exposed to Bortezomib	N	SVd Arm	61	33	54,10	28	45,90	4,86	2,10	NA	2,74	1,47	5,10	0,0009	0,6572
Patients with at least one AESI or AECI Thrombocytopenia	Previously Exposed to Bortezomib	N	Vd Arm	62	15	24,19	47	75,81	NA	NA	NA	-	-	-	-	0,6572
Patients with at least one AESI or AECI Thrombocytopenia	Previously Exposed to Bortezomib	Y	SVd Arm	134	88	65,67	46	34,33	1,68	1,41	4,17	3,23	2,21	4,73	0,0000	0,6572
Patients with at least one AESI or AECI Thrombocytopenia	Previously Exposed to Bortezomib	Y	Vd Arm	142	41	28,87	101	71,13	NA	NA	NA	-	-	-	-	0,6572
Patients with at least one AESI or AECI Neutropenia	total	-	SVd Arm	195	32	16,41	163	83,59	NA	44,52	NA	2,62	1,37	5,02	0,0025	NA
Patients with at least one AESI or AECI Neutropenia	total	-	Vd Arm	204	13	6,37	191	93,63	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Neutropenia	Gender	Female	SVd Arm	80	16	20,00	64	80,00	NA	NA	NA	2,45	1,03	5,86	0,0377	0,8149
Patients with at least one AESI or AECI Neutropenia	Gender	Female	Vd Arm	91	8	8,79	83	91,21	NA	NA	NA	-	-	-	-	0,8149

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Neutropenia	Gender	Male	SVd Arm	115	16	13,91	99	86,09	NA	44,52	NA	2,88	1,04	7,96	0,0332	0,8149
Patients with at least one AESI or AECI Neutropenia	Gender	Male	Vd Arm	113	5	4,42	108	95,58	NA	NA	NA	-	-	-	-	0,8149
Patients with at least one AESI or AECI Neutropenia	Age Group	<65	SVd Arm	86	17	19,77	69	80,23	NA	NA	NA	7,58	1,73	33,17	0,0017	0,0633
Patients with at least one AESI or AECI Neutropenia	Age Group	<65	Vd Arm	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,0633
Patients with at least one AESI or AECI Neutropenia	Age Group	>=65	SVd Arm	109	15	13,76	94	86,24	NA	44,52	NA	1,55	0,70	3,43	0,2798	0,0633
Patients with at least one AESI or AECI Neutropenia	Age Group	>=65	Vd Arm	129	11	8,53	118	91,47	NA	NA	NA	-	-	-	-	0,0633
Patients with at least one AESI or AECI Neutropenia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	28	16,18	145	83,82	NA	44,52	NA	2,52	1,25	5,09	0,0075	0,8811
Patients with at least one AESI or AECI Neutropenia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	11	6,32	163	93,68	NA	NA	NA	-	-	-	-	0,8811
Patients with at least one AESI or AECI Neutropenia	Baseline R-ISS stage	Stage III	SVd Arm	12	3	25,00	9	75,00	NA	NA	NA	2,94	0,45	19,05	0,2415	0,8811
Patients with at least one AESI or AECI Neutropenia	Baseline R-ISS stage	Stage III	Vd Arm	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,8811
Patients with at least one AESI or AECI Neutropenia	Baseline ISS stage	Stage I or II	SVd Arm	163	28	17,18	135	82,82	NA	44,52	NA	2,64	1,31	5,33	0,0047	0,8714
Patients with at least one AESI or AECI Neutropenia	Baseline ISS stage	Stage I or II	Vd Arm	173	11	6,36	162	93,64	NA	NA	NA	-	-	-	-	0,8714
Patients with at least one AESI or AECI Neutropenia	Baseline ISS stage	Stage III	SVd Arm	32	4	12,50	28	87,50	NA	NA	NA	2,27	0,41	12,45	0,3315	0,8714
Patients with at least one AESI or AECI Neutropenia	Baseline ISS stage	Stage III	Vd Arm	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,8714
Patients with at least one AESI or AECI Neutropenia	Region (SAP)	Region 1	SVd Arm	18	2	11,11	16	88,89	-	-	-	-	-	-	-	0,0678
Patients with at least one AESI or AECI Neutropenia	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,0678
Patients with at least one AESI or AECI Neutropenia	Region (SAP)	Region 2	SVd Arm	61	11	18,03	50	81,97	44,52	27,07	NA	2,95	0,90	9,70	0,0635	0,0678
Patients with at least one AESI or AECI Neutropenia	Region (SAP)	Region 2	Vd Arm	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,0678
Patients with at least one AESI or AECI Neutropenia	Region (SAP)	Region 3	SVd Arm	47	5	10,64	42	89,36	NA	NA	NA	0,93	0,27	3,25	0,9077	0,0678
Patients with at least one AESI or AECI Neutropenia	Region (SAP)	Region 3	Vd Arm	53	5	9,43	48	90,57	NA	NA	NA	-	-	-	-	0,0678
Patients with at least one AESI or AECI Neutropenia	Region (SAP)	Region 4	SVd Arm	69	14	20,29	55	79,71	NA	NA	NA	9,13	2,06	40,35	0,0004	0,0678
Patients with at least one AESI or AECI Neutropenia	Region (SAP)	Region 4	Vd Arm	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,0678
Patients with at least one AESI or AECI Neutropenia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	19	16,24	98	83,76	NA	44,52	NA	1,97	0,92	4,19	0,0737	0,1383
Patients with at least one AESI or AECI Neutropenia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	11	8,09	125	91,91	NA	NA	NA	-	-	-	-	0,1383
Patients with at least one AESI or AECI Neutropenia	Region (by medical care situation)	Rest of the world	SVd Arm	78	13	16,67	65	83,33	NA	NA	NA	6,98	1,56	31,16	0,0032	0,1383
Patients with at least one AESI or AECI Neutropenia	Region (by medical care situation)	Rest of the world	Vd Arm	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,1383
Patients with at least one AESI or AECI Neutropenia	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	2,12	0,19	23,75	0,5333	0,9011
Patients with at least one AESI or AECI Neutropenia	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,9011
Patients with at least one AESI or AECI Neutropenia	Race	White	SVd Arm	161	30	18,63	131	81,37	44,52	44,52	NA	2,48	1,26	4,89	0,0065	0,9011
Patients with at least one AESI or AECI Neutropenia	Race	White	Vd Arm	162	12	7,41	150	92,59	NA	NA	NA	-	-	-	-	0,9011

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Neutropenia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Neutropenia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Neutropenia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	28	16,37	143	83,63	NA	44,52	NA	2,29	1,18	4,45	0,0118	NA
Patients with at least one AESI or AECI Neutropenia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	13	7,03	172	92,97	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Neutropenia	Prior PI therapies	N	SVd Arm	48	4	8,33	44	91,67	NA	NA	NA	1,80	0,33	9,85	0,4916	0,6424
Patients with at least one AESI or AECI Neutropenia	Prior PI therapies	N	Vd Arm	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,6424
Patients with at least one AESI or AECI Neutropenia	Prior PI therapies	Y	SVd Arm	147	28	19,05	119	80,95	44,52	44,52	NA	2,78	1,38	5,62	0,0029	0,6424
Patients with at least one AESI or AECI Neutropenia	Prior PI therapies	Y	Vd Arm	157	11	7,01	146	92,99	NA	NA	NA	-	-	-	-	0,6424
Patients with at least one AESI or AECI Neutropenia	Prior anti-MM regimen	>1	SVd Arm	98	17	17,35	81	82,65	44,52	NA	NA	2,51	1,03	6,13	0,0357	0,8916
Patients with at least one AESI or AECI Neutropenia	Prior anti-MM regimen	>1	Vd Arm	104	7	6,73	97	93,27	NA	NA	NA	-	-	-	-	0,8916
Patients with at least one AESI or AECI Neutropenia	Prior anti-MM regimen	1	SVd Arm	97	15	15,46	82	84,54	NA	NA	NA	2,75	1,07	7,11	0,0293	0,8916
Patients with at least one AESI or AECI Neutropenia	Prior anti-MM regimen	1	Vd Arm	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,8916
Patients with at least one AESI or AECI Neutropenia	Baseline single cytogenetic alterations	N	SVd Arm	98	10	10,20	88	89,80	44,52	44,52	NA	1,93	0,68	5,45	0,2093	0,4296
Patients with at least one AESI or AECI Neutropenia	Baseline single cytogenetic alterations	N	Vd Arm	111	6	5,41	105	94,59	NA	NA	NA	-	-	-	-	0,4296
Patients with at least one AESI or AECI Neutropenia	Baseline single cytogenetic alterations	Y	SVd Arm	97	22	22,68	75	77,32	NA	27,07	NA	3,31	1,41	7,80	0,0037	0,4296
Patients with at least one AESI or AECI Neutropenia	Baseline single cytogenetic alterations	Y	Vd Arm	93	7	7,53	86	92,47	NA	NA	NA	-	-	-	-	0,4296
Patients with at least one AESI or AECI Neutropenia	Previously Exposed to Bortezomib	N	SVd Arm	61	6	9,84	55	90,16	NA	NA	NA	2,38	0,57	9,89	0,2222	0,7999
Patients with at least one AESI or AECI Neutropenia	Previously Exposed to Bortezomib	N	Vd Arm	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,7999
Patients with at least one AESI or AECI Neutropenia	Previously Exposed to Bortezomib	Y	SVd Arm	134	26	19,40	108	80,60	44,52	44,52	NA	2,92	1,40	6,11	0,0028	0,7999
Patients with at least one AESI or AECI Neutropenia	Previously Exposed to Bortezomib	Y	Vd Arm	142	10	7,04	132	92,96	NA	NA	NA	-	-	-	-	0,7999
Patients with at least one AESI or AECI Nausea	total	-	SVd Arm	195	98	50,26	97	49,74	4,60	2,56	NA	6,60	4,11	10,60	0,0000	NA
Patients with at least one AESI or AECI Nausea	total	-	Vd Arm	204	21	10,29	183	89,71	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Nausea	Gender	Female	SVd Arm	80	46	57,50	34	42,50	2,99	1,45	NA	7,41	3,60	15,28	0,0000	0,8639
Patients with at least one AESI or AECI Nausea	Gender	Female	Vd Arm	91	11	12,09	80	87,91	NA	NA	NA	-	-	-	-	0,8639
Patients with at least one AESI or AECI Nausea	Gender	Male	SVd Arm	115	52	45,22	63	54,78	17,28	3,94	NA	6,79	3,43	13,48	0,0000	0,8639
Patients with at least one AESI or AECI Nausea	Gender	Male	Vd Arm	113	10	8,85	103	91,15	NA	NA	NA	-	-	-	-	0,8639
Patients with at least one AESI or AECI Nausea	Age Group	<65	SVd Arm	86	41	47,67	45	52,33	NA	2,17	NA	5,53	2,57	11,92	0,0000	0,4251
Patients with at least one AESI or AECI Nausea	Age Group	<65	Vd Arm	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,4251
Patients with at least one AESI or AECI Nausea	Age Group	>=65	SVd Arm	109	57	52,29	52	47,71	4,47	1,87	NA	8,33	4,35	15,95	0,0000	0,4251

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Nausea	Age Group	>=65	Vd Arm	129	13	10,08	116	89,92	NA	NA	NA	-	-	-	-	0,4251
Patients with at least one AESI or AECI Nausea	Baseline R-ISS stage	Stage I or II	SVd Arm	173	88	50,87	85	49,13	4,60	2,56	NA	6,24	3,79	10,26	0,0000	0,8756
Patients with at least one AESI or AECI Nausea	Baseline R-ISS stage	Stage I or II	Vd Arm	174	19	10,92	155	89,08	NA	NA	NA	-	-	-	-	0,8756
Patients with at least one AESI or AECI Nausea	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	NA	1,05	NA	7,48	0,81	68,93	0,0452	0,8756
Patients with at least one AESI or AECI Nausea	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,8756
Patients with at least one AESI or AECI Nausea	Baseline ISS stage	Stage I or II	SVd Arm	163	91	55,83	72	44,17	3,94	1,68	17,28	7,48	4,50	12,41	0,0000	0,5038
Patients with at least one AESI or AECI Nausea	Baseline ISS stage	Stage I or II	Vd Arm	173	19	10,98	154	89,02	NA	NA	NA	-	-	-	-	0,5038
Patients with at least one AESI or AECI Nausea	Baseline ISS stage	Stage III	SVd Arm	32	7	21,88	25	78,12	NA	NA	NA	4,25	0,88	20,56	0,0506	0,5038
Patients with at least one AESI or AECI Nausea	Baseline ISS stage	Stage III	Vd Arm	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,5038
Patients with at least one AESI or AECI Nausea	Region (SAP)	Region 1	SVd Arm	18	14	77,78	4	22,22	0,10	0,07	NA	17,12	2,20	133,11	0,0003	0,6751
Patients with at least one AESI or AECI Nausea	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,6751
Patients with at least one AESI or AECI Nausea	Region (SAP)	Region 2	SVd Arm	61	34	55,74	27	44,26	2,10	0,16	NA	5,51	2,61	11,63	0,0000	0,6751
Patients with at least one AESI or AECI Nausea	Region (SAP)	Region 2	Vd Arm	64	9	14,06	55	85,94	NA	NA	NA	-	-	-	-	0,6751
Patients with at least one AESI or AECI Nausea	Region (SAP)	Region 3	SVd Arm	47	17	36,17	30	63,83	NA	17,28	NA	10,12	2,32	44,03	0,0001	0,6751
Patients with at least one AESI or AECI Nausea	Region (SAP)	Region 3	Vd Arm	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,6751
Patients with at least one AESI or AECI Nausea	Region (SAP)	Region 4	SVd Arm	69	33	47,83	36	52,17	8,31	2,56	NA	5,57	2,56	12,11	0,0000	0,6751
Patients with at least one AESI or AECI Nausea	Region (SAP)	Region 4	Vd Arm	70	8	11,43	62	88,57	NA	32,53	NA	-	-	-	-	0,6751
Patients with at least one AESI or AECI Nausea	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	57	48,72	60	51,28	8,31	3,94	NA	6,32	3,44	11,58	0,0000	0,9611
Patients with at least one AESI or AECI Nausea	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,9611
Patients with at least one AESI or AECI Nausea	Region (by medical care situation)	Rest of the world	SVd Arm	78	41	52,56	37	47,44	3,35	1,64	NA	6,16	2,88	13,21	0,0000	0,9611
Patients with at least one AESI or AECI Nausea	Region (by medical care situation)	Rest of the world	Vd Arm	68	8	11,76	60	88,24	NA	32,53	NA	-	-	-	-	0,9611
Patients with at least one AESI or AECI Nausea	Race	Races other than White	SVd Arm	34	20	58,82	14	41,18	2,00	1,05	NA	11,01	3,58	33,90	0,0000	0,4032
Patients with at least one AESI or AECI Nausea	Race	Races other than White	Vd Arm	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,4032
Patients with at least one AESI or AECI Nausea	Race	White	SVd Arm	161	78	48,45	83	51,55	9,26	3,94	NA	6,46	3,76	11,12	0,0000	0,4032
Patients with at least one AESI or AECI Nausea	Race	White	Vd Arm	162	16	9,88	146	90,12	NA	NA	NA	-	-	-	-	0,4032
Patients with at least one AESI or AECI Nausea	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Nausea	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Nausea	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	86	50,29	85	49,71	6,01	2,56	NA	6,53	3,96	10,77	0,0000	NA
Patients with at least one AESI or AECI Nausea	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	20	10,81	165	89,19	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Nausea	Prior PI therapies	N	SVd Arm	48	25	52,08	23	47,92	3,98	1,68	NA	6,68	2,53	17,62	0,0000	0,9765
Patients with at least one AESI or AECI Nausea	Prior PI therapies	N	Vd Arm	47	5	10,64	42	89,36	NA	32,53	NA	-	-	-	-	0,9765
Patients with at least one AESI or AECI Nausea	Prior PI therapies	Y	SVd Arm	147	73	49,66	74	50,34	6,01	2,10	NA	6,57	3,82	11,31	0,0000	0,9765
Patients with at least one AESI or AECI Nausea	Prior PI therapies	Y	Vd Arm	157	16	10,19	141	89,81	NA	NA	NA	-	-	-	-	0,9765
Patients with at least one AESI or AECI Nausea	Prior anti-MM regimen	>1	SVd Arm	98	49	50,00	49	50,00	8,31	2,00	NA	7,87	3,85	16,07	0,0000	0,4970
Patients with at least one AESI or AECI Nausea	Prior anti-MM regimen	>1	Vd Arm	104	9	8,65	95	91,35	NA	NA	NA	-	-	-	-	0,4970
Patients with at least one AESI or AECI Nausea	Prior anti-MM regimen	1	SVd Arm	97	49	50,52	48	49,48	4,04	2,79	NA	5,65	2,99	10,67	0,0000	0,4970
Patients with at least one AESI or AECI Nausea	Prior anti-MM regimen	1	Vd Arm	100	12	12,00	88	88,00	NA	NA	NA	-	-	-	-	0,4970
Patients with at least one AESI or AECI Nausea	Baseline single cytogenetic alterations	N	SVd Arm	98	47	47,96	51	52,04	17,28	2,56	NA	5,26	2,88	9,63	0,0000	0,1861
Patients with at least one AESI or AECI Nausea	Baseline single cytogenetic alterations	N	Vd Arm	111	14	12,61	97	87,39	NA	NA	NA	-	-	-	-	0,1861
Patients with at least one AESI or AECI Nausea	Baseline single cytogenetic alterations	Y	SVd Arm	97	51	52,58	46	47,42	4,47	1,87	NA	10,63	4,55	24,87	0,0000	0,1861
Patients with at least one AESI or AECI Nausea	Baseline single cytogenetic alterations	Y	Vd Arm	93	7	7,53	86	92,47	NA	32,53	NA	-	-	-	-	0,1861
Patients with at least one AESI or AECI Nausea	Previously Exposed to Bortezomib	N	SVd Arm	61	31	50,82	30	49,18	4,04	1,68	NA	6,06	2,64	13,92	0,0000	0,8087
Patients with at least one AESI or AECI Nausea	Previously Exposed to Bortezomib	N	Vd Arm	62	7	11,29	55	88,71	NA	32,53	NA	-	-	-	-	0,8087
Patients with at least one AESI or AECI Nausea	Previously Exposed to Bortezomib	Y	SVd Arm	134	67	50,00	67	50,00	6,01	2,10	NA	6,87	3,85	12,26	0,0000	0,8087
Patients with at least one AESI or AECI Nausea	Previously Exposed to Bortezomib	Y	Vd Arm	142	14	9,86	128	90,14	NA	NA	NA	-	-	-	-	0,8087
Patients with at least one AESI or AECI Vomiting	total	-	SVd Arm	195	40	20,51	155	79,49	NA	NA	NA	4,57	2,27	9,19	0,0000	NA
Patients with at least one AESI or AECI Vomiting	total	-	Vd Arm	204	10	4,90	194	95,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Vomiting	Gender	Female	SVd Arm	80	25	31,25	55	68,75	NA	NA	NA	7,96	2,74	23,07	0,0000	0,0694
Patients with at least one AESI or AECI Vomiting	Gender	Female	Vd Arm	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,0694
Patients with at least one AESI or AECI Vomiting	Gender	Male	SVd Arm	115	15	13,04	100	86,96	NA	NA	NA	2,11	0,80	5,51	0,1215	0,0694
Patients with at least one AESI or AECI Vomiting	Gender	Male	Vd Arm	113	6	5,31	107	94,69	NA	NA	NA	-	-	-	-	0,0694
Patients with at least one AESI or AECI Vomiting	Age Group	<65	SVd Arm	86	20	23,26	66	76,74	NA	NA	NA	6,93	2,03	23,64	0,0004	0,3573
Patients with at least one AESI or AECI Vomiting	Age Group	<65	Vd Arm	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,3573
Patients with at least one AESI or AECI Vomiting	Age Group	>=65	SVd Arm	109	20	18,35	89	81,65	NA	NA	NA	3,42	1,44	8,14	0,0032	0,3573
Patients with at least one AESI or AECI Vomiting	Age Group	>=65	Vd Arm	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	0,3573
Patients with at least one AESI or AECI Vomiting	Baseline R-ISS stage	Stage I or II	SVd Arm	173	38	21,97	135	78,03	NA	NA	NA	5,22	2,43	11,20	0,0000	0,1154
Patients with at least one AESI or AECI Vomiting	Baseline R-ISS stage	Stage I or II	Vd Arm	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	0,1154
Patients with at least one AESI or AECI Vomiting	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	NA	NA	NA	0,59	0,04	7,96	0,6925	0,1154
Patients with at least one AESI or AECI Vomiting	Baseline R-ISS stage	Stage III	Vd Arm	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,1154

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Vomiting	Baseline ISS stage	Stage I or II	SVd Arm	163	36	22,09	127	77,91	NA	NA	NA	4,64	2,23	9,63	0,0000	0,7250
Patients with at least one AESI or AECI Vomiting	Baseline ISS stage	Stage I or II	Vd Arm	173	9	5,20	164	94,80	NA	NA	NA	-	-	-	-	0,7250
Patients with at least one AESI or AECI Vomiting	Baseline ISS stage	Stage III	SVd Arm	32	4	12,50	28	87,50	NA	NA	NA	3,02	0,31	29,38	0,3174	0,7250
Patients with at least one AESI or AECI Vomiting	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,7250
Patients with at least one AESI or AECI Vomiting	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	NA	NA	NA	1,35	0,22	8,41	0,7447	0,4007
Patients with at least one AESI or AECI Vomiting	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,4007
Patients with at least one AESI or AECI Vomiting	Region (SAP)	Region 2	SVd Arm	61	16	26,23	45	73,77	NA	9,26	NA	6,21	1,79	21,53	0,0011	0,4007
Patients with at least one AESI or AECI Vomiting	Region (SAP)	Region 2	Vd Arm	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,4007
Patients with at least one AESI or AECI Vomiting	Region (SAP)	Region 3	SVd Arm	47	4	8,51	43	91,49	-	-	-	-	-	-	-	0,4007
Patients with at least one AESI or AECI Vomiting	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,4007
Patients with at least one AESI or AECI Vomiting	Region (SAP)	Region 4	SVd Arm	69	17	24,64	52	75,36	NA	NA	NA	3,76	1,36	10,39	0,0062	0,4007
Patients with at least one AESI or AECI Vomiting	Region (SAP)	Region 4	Vd Arm	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,4007
Patients with at least one AESI or AECI Vomiting	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	20	17,09	97	82,91	NA	NA	NA	4,83	1,80	12,99	0,0006	0,7071
Patients with at least one AESI or AECI Vomiting	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,7071
Patients with at least one AESI or AECI Vomiting	Region (by medical care situation)	Rest of the world	SVd Arm	78	20	25,64	58	74,36	NA	13,11	NA	3,69	1,37	9,99	0,0059	0,7071
Patients with at least one AESI or AECI Vomiting	Region (by medical care situation)	Rest of the world	Vd Arm	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,7071
Patients with at least one AESI or AECI Vomiting	Race	Races other than White	SVd Arm	34	13	38,24	21	61,76	NA	13,11	NA	2,86	1,04	7,86	0,0348	0,1214
Patients with at least one AESI or AECI Vomiting	Race	Races other than White	Vd Arm	42	7	16,67	35	83,33	NA	NA	NA	-	-	-	-	0,1214
Patients with at least one AESI or AECI Vomiting	Race	White	SVd Arm	161	27	16,77	134	83,23	NA	NA	NA	9,93	2,97	33,22	0,0000	0,1214
Patients with at least one AESI or AECI Vomiting	Race	White	Vd Arm	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	0,1214
Patients with at least one AESI or AECI Vomiting	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Vomiting	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Vomiting	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	33	19,30	138	80,70	NA	NA	NA	4,73	2,17	10,32	0,0000	NA
Patients with at least one AESI or AECI Vomiting	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	8	4,32	177	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Vomiting	Prior PI therapies	N	SVd Arm	48	13	27,08	35	72,92	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Vomiting	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Vomiting	Prior PI therapies	Y	SVd Arm	147	27	18,37	120	81,63	NA	NA	NA	3,05	1,47	6,31	0,0016	NA
Patients with at least one AESI or AECI Vomiting	Prior PI therapies	Y	Vd Arm	157	10	6,37	147	93,63	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Vomiting	Prior anti-MM regimen	>1	SVd Arm	98	24	24,49	74	75,51	NA	NA	NA	4,35	1,77	10,70	0,0005	0,8715

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Vomiting	Prior anti-MM regimen	>1	Vd Arm	104	6	5,77	98	94,23	NA	NA	NA	-	-	-	-	0,8715
Patients with at least one AESI or AECI Vomiting	Prior anti-MM regimen	1	SVd Arm	97	16	16,49	81	83,51	NA	NA	NA	4,90	1,61	14,88	0,0020	0,8715
Patients with at least one AESI or AECI Vomiting	Prior anti-MM regimen	1	Vd Arm	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,8715
Patients with at least one AESI or AECI Vomiting	Baseline single cytogenetic alterations	N	SVd Arm	98	21	21,43	77	78,57	NA	NA	NA	4,58	1,83	11,51	0,0004	0,9404
Patients with at least one AESI or AECI Vomiting	Baseline single cytogenetic alterations	N	Vd Arm	111	6	5,41	105	94,59	NA	NA	NA	-	-	-	-	0,9404
Patients with at least one AESI or AECI Vomiting	Baseline single cytogenetic alterations	Y	SVd Arm	97	19	19,59	78	80,41	NA	NA	NA	4,34	1,47	12,80	0,0037	0,9404
Patients with at least one AESI or AECI Vomiting	Baseline single cytogenetic alterations	Y	Vd Arm	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,9404
Patients with at least one AESI or AECI Vomiting	Previously Exposed to Bortezomib	N	SVd Arm	61	15	24,59	46	75,41	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Vomiting	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Vomiting	Previously Exposed to Bortezomib	Y	SVd Arm	134	25	18,66	109	81,34	NA	NA	NA	2,90	1,39	6,05	0,0030	NA
Patients with at least one AESI or AECI Vomiting	Previously Exposed to Bortezomib	Y	Vd Arm	142	10	7,04	132	92,96	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Decreased Appetite	total	-	SVd Arm	195	70	35,90	125	64,10	NA	NA	NA	7,82	4,14	14,79	0,0000	NA
Patients with at least one AESI or AECI Decreased Appetite	total	-	Vd Arm	204	11	5,39	193	94,61	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Decreased Appetite	Gender	Female	SVd Arm	80	32	40,00	48	60,00	NA	7,85	NA	13,24	4,03	43,52	0,0000	0,2217
Patients with at least one AESI or AECI Decreased Appetite	Gender	Female	Vd Arm	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,2217
Patients with at least one AESI or AECI Decreased Appetite	Gender	Male	SVd Arm	115	38	33,04	77	66,96	NA	NA	NA	5,47	2,53	11,81	0,0000	0,2217
Patients with at least one AESI or AECI Decreased Appetite	Gender	Male	Vd Arm	113	8	7,08	105	92,92	NA	NA	NA	-	-	-	-	0,2217
Patients with at least one AESI or AECI Decreased Appetite	Age Group	<65	SVd Arm	86	29	33,72	57	66,28	NA	NA	NA	3,54	1,60	7,84	0,0010	0,0177
Patients with at least one AESI or AECI Decreased Appetite	Age Group	<65	Vd Arm	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,0177
Patients with at least one AESI or AECI Decreased Appetite	Age Group	>=65	SVd Arm	109	41	37,61	68	62,39	NA	11,53	NA	19,72	6,09	63,89	0,0000	0,0177
Patients with at least one AESI or AECI Decreased Appetite	Age Group	>=65	Vd Arm	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	0,0177
Patients with at least one AESI or AECI Decreased Appetite	Baseline R-ISS stage	Stage I or II	SVd Arm	173	60	34,68	113	65,32	NA	NA	NA	7,88	3,90	15,89	0,0000	0,7095
Patients with at least one AESI or AECI Decreased Appetite	Baseline R-ISS stage	Stage I or II	Vd Arm	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	0,7095
Patients with at least one AESI or AECI Decreased Appetite	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	NA	1,64	NA	5,05	0,54	47,17	0,1254	0,7095
Patients with at least one AESI or AECI Decreased Appetite	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,7095
Patients with at least one AESI or AECI Decreased Appetite	Baseline ISS stage	Stage I or II	SVd Arm	163	55	33,74	108	66,26	NA	NA	NA	8,56	4,07	17,98	0,0000	0,6468
Patients with at least one AESI or AECI Decreased Appetite	Baseline ISS stage	Stage I or II	Vd Arm	173	8	4,62	165	95,38	NA	NA	NA	-	-	-	-	0,6468
Patients with at least one AESI or AECI Decreased Appetite	Baseline ISS stage	Stage III	SVd Arm	32	15	46,88	17	53,12	5,59	2,56	NA	6,10	1,75	21,19	0,0012	0,6468
Patients with at least one AESI or AECI Decreased Appetite	Baseline ISS stage	Stage III	Vd Arm	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,6468
Patients with at least one AESI or AECI Decreased Appetite	Region (SAP)	Region 1	SVd Arm	18	8	44,44	10	55,56	-	-	-	-	-	-	-	0,6046

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Decreased Appetite	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,6046
Patients with at least one AESI or AECI Decreased Appetite	Region (SAP)	Region 2	SVd Arm	61	28	45,90	33	54,10	7,85	2,63	NA	8,72	3,03	25,07	0,0000	0,6046
Patients with at least one AESI or AECI Decreased Appetite	Region (SAP)	Region 2	Vd Arm	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,6046
Patients with at least one AESI or AECI Decreased Appetite	Region (SAP)	Region 3	SVd Arm	47	11	23,40	36	76,60	NA	NA	NA	10,15	1,31	78,82	0,0062	0,6046
Patients with at least one AESI or AECI Decreased Appetite	Region (SAP)	Region 3	Vd Arm	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,6046
Patients with at least one AESI or AECI Decreased Appetite	Region (SAP)	Region 4	SVd Arm	69	23	33,33	46	66,67	NA	NA	NA	4,65	1,89	11,46	0,0002	0,6046
Patients with at least one AESI or AECI Decreased Appetite	Region (SAP)	Region 4	Vd Arm	70	6	8,57	64	91,43	NA	NA	NA	-	-	-	-	0,6046
Patients with at least one AESI or AECI Decreased Appetite	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	40	34,19	77	65,81	NA	NA	NA	13,16	4,69	36,93	0,0000	0,1261
Patients with at least one AESI or AECI Decreased Appetite	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	4	2,94	132	97,06	NA	NA	NA	-	-	-	-	0,1261
Patients with at least one AESI or AECI Decreased Appetite	Region (by medical care situation)	Rest of the world	SVd Arm	78	30	38,46	48	61,54	NA	4,63	NA	4,68	2,04	10,74	0,0001	0,1261
Patients with at least one AESI or AECI Decreased Appetite	Region (by medical care situation)	Rest of the world	Vd Arm	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,1261
Patients with at least one AESI or AECI Decreased Appetite	Race	Races other than White	SVd Arm	34	17	50,00	17	50,00	4,27	1,25	NA	3,70	1,51	9,07	0,0023	0,0222
Patients with at least one AESI or AECI Decreased Appetite	Race	Races other than White	Vd Arm	42	8	19,05	34	80,95	NA	21,52	NA	-	-	-	-	0,0222
Patients with at least one AESI or AECI Decreased Appetite	Race	White	SVd Arm	161	53	32,92	108	67,08	NA	NA	NA	20,57	6,41	65,95	0,0000	0,0222
Patients with at least one AESI or AECI Decreased Appetite	Race	White	Vd Arm	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	0,0222
Patients with at least one AESI or AECI Decreased Appetite	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Decreased Appetite	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Decreased Appetite	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	55	32,16	116	67,84	NA	NA	NA	6,28	3,27	12,04	0,0000	NA
Patients with at least one AESI or AECI Decreased Appetite	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	11	5,95	174	94,05	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Decreased Appetite	Prior PI therapies	N	SVd Arm	48	19	39,58	29	60,42	NA	4,01	NA	11,48	2,66	49,49	0,0000	0,5515
Patients with at least one AESI or AECI Decreased Appetite	Prior PI therapies	N	Vd Arm	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,5515
Patients with at least one AESI or AECI Decreased Appetite	Prior PI therapies	Y	SVd Arm	147	51	34,69	96	65,31	NA	NA	NA	7,01	3,45	14,25	0,0000	0,5515
Patients with at least one AESI or AECI Decreased Appetite	Prior PI therapies	Y	Vd Arm	157	9	5,73	148	94,27	NA	NA	NA	-	-	-	-	0,5515
Patients with at least one AESI or AECI Decreased Appetite	Prior anti-MM regimen	>1	SVd Arm	98	35	35,71	63	64,29	NA	11,53	NA	5,37	2,49	11,60	0,0000	0,1716
Patients with at least one AESI or AECI Decreased Appetite	Prior anti-MM regimen	>1	Vd Arm	104	8	7,69	96	92,31	NA	NA	NA	-	-	-	-	0,1716
Patients with at least one AESI or AECI Decreased Appetite	Prior anti-MM regimen	1	SVd Arm	97	35	36,08	62	63,92	NA	NA	NA	14,36	4,41	46,77	0,0000	0,1716
Patients with at least one AESI or AECI Decreased Appetite	Prior anti-MM regimen	1	Vd Arm	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,1716
Patients with at least one AESI or AECI Decreased Appetite	Baseline single cytogenetic alterations	N	SVd Arm	98	36	36,73	62	63,27	NA	8,61	NA	6,53	3,01	14,18	0,0000	0,4530
Patients with at least one AESI or AECI Decreased Appetite	Baseline single cytogenetic alterations	N	Vd Arm	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,4530

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Decreased Appetite	Baseline single cytogenetic alterations	Y	SVd Arm	97	34	35,05	63	64,95	NA	NA	NA	11,22	3,44	36,60	0,0000	0,4530
Patients with at least one AESI or AECI Decreased Appetite	Baseline single cytogenetic alterations	Y	Vd Arm	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,4530
Patients with at least one AESI or AECI Decreased Appetite	Previously Exposed to Bortezomib	N	SVd Arm	61	26	42,62	35	57,38	NA	3,48	NA	16,77	3,95	71,16	0,0000	0,2153
Patients with at least one AESI or AECI Decreased Appetite	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,2153
Patients with at least one AESI or AECI Decreased Appetite	Previously Exposed to Bortezomib	Y	SVd Arm	134	44	32,84	90	67,16	NA	NA	NA	6,04	2,94	12,41	0,0000	0,2153
Patients with at least one AESI or AECI Decreased Appetite	Previously Exposed to Bortezomib	Y	Vd Arm	142	9	6,34	133	93,66	NA	NA	NA	-	-	-	-	0,2153
Patients with at least one AESI or AECI Weight Decreased	total	-	SVd Arm	195	51	26,15	144	73,85	NA	NA	NA	2,52	1,55	4,08	0,0001	NA
Patients with at least one AESI or AECI Weight Decreased	total	-	Vd Arm	204	25	12,25	179	87,75	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Weight Decreased	Gender	Female	SVd Arm	80	24	30,00	56	70,00	NA	NA	NA	6,12	2,45	15,28	0,0000	0,0111
Patients with at least one AESI or AECI Weight Decreased	Gender	Female	Vd Arm	91	6	6,59	85	93,41	NA	NA	NA	-	-	-	-	0,0111
Patients with at least one AESI or AECI Weight Decreased	Gender	Male	SVd Arm	115	27	23,48	88	76,52	NA	NA	NA	1,49	0,82	2,69	0,1891	0,0111
Patients with at least one AESI or AECI Weight Decreased	Gender	Male	Vd Arm	113	19	16,81	94	83,19	NA	NA	NA	-	-	-	-	0,0111
Patients with at least one AESI or AECI Weight Decreased	Age Group	<65	SVd Arm	86	21	24,42	65	75,58	NA	NA	NA	2,08	0,93	4,65	0,0687	0,5751
Patients with at least one AESI or AECI Weight Decreased	Age Group	<65	Vd Arm	75	9	12,00	66	88,00	NA	NA	NA	-	-	-	-	0,5751
Patients with at least one AESI or AECI Weight Decreased	Age Group	>=65	SVd Arm	109	30	27,52	79	72,48	NA	NA	NA	2,78	1,50	5,15	0,0007	0,5751
Patients with at least one AESI or AECI Weight Decreased	Age Group	>=65	Vd Arm	129	16	12,40	113	87,60	NA	NA	NA	-	-	-	-	0,5751
Patients with at least one AESI or AECI Weight Decreased	Baseline R-ISS stage	Stage I or II	SVd Arm	173	42	24,28	131	75,72	NA	NA	NA	2,62	1,50	4,55	0,0004	0,7197
Patients with at least one AESI or AECI Weight Decreased	Baseline R-ISS stage	Stage I or II	Vd Arm	174	18	10,34	156	89,66	NA	NA	NA	-	-	-	-	0,7197
Patients with at least one AESI or AECI Weight Decreased	Baseline R-ISS stage	Stage III	SVd Arm	12	7	58,33	5	41,67	3,02	1,64	NA	3,47	0,82	14,59	0,0772	0,7197
Patients with at least one AESI or AECI Weight Decreased	Baseline R-ISS stage	Stage III	Vd Arm	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,7197
Patients with at least one AESI or AECI Weight Decreased	Baseline ISS stage	Stage I or II	SVd Arm	163	39	23,93	124	76,07	NA	NA	NA	2,28	1,33	3,91	0,0021	0,5712
Patients with at least one AESI or AECI Weight Decreased	Baseline ISS stage	Stage I or II	Vd Arm	173	20	11,56	153	88,44	NA	NA	NA	-	-	-	-	0,5712
Patients with at least one AESI or AECI Weight Decreased	Baseline ISS stage	Stage III	SVd Arm	32	12	37,50	20	62,50	8,28	3,02	NA	3,22	1,11	9,28	0,0231	0,5712
Patients with at least one AESI or AECI Weight Decreased	Baseline ISS stage	Stage III	Vd Arm	31	5	16,13	26	83,87	NA	NA	NA	-	-	-	-	0,5712
Patients with at least one AESI or AECI Weight Decreased	Region (SAP)	Region 1	SVd Arm	18	4	22,22	14	77,78	NA	NA	NA	3,32	0,37	30,05	0,2580	0,9800
Patients with at least one AESI or AECI Weight Decreased	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,9800
Patients with at least one AESI or AECI Weight Decreased	Region (SAP)	Region 2	SVd Arm	61	13	21,31	48	78,69	NA	NA	NA	2,35	0,89	6,22	0,0759	0,9800
Patients with at least one AESI or AECI Weight Decreased	Region (SAP)	Region 2	Vd Arm	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,9800
Patients with at least one AESI or AECI Weight Decreased	Region (SAP)	Region 3	SVd Arm	47	9	19,15	38	80,85	NA	NA	NA	2,12	0,65	6,97	0,2036	0,9800
Patients with at least one AESI or AECI Weight Decreased	Region (SAP)	Region 3	Vd Arm	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,9800

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Weight Decreased	Region (SAP)	Region 4	SVd Arm	69	25	36,23	44	63,77	NA	5,78	NA	2,66	1,36	5,19	0,0029	0,9800
Patients with at least one AESI or AECI Weight Decreased	Region (SAP)	Region 4	Vd Arm	70	14	20,00	56	80,00	NA	NA	NA	-	-	-	-	0,9800
Patients with at least one AESI or AECI Weight Decreased	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	24	20,51	93	79,49	NA	NA	NA	2,58	1,25	5,30	0,0076	0,9891
Patients with at least one AESI or AECI Weight Decreased	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	11	8,09	125	91,91	NA	NA	NA	-	-	-	-	0,9891
Patients with at least one AESI or AECI Weight Decreased	Region (by medical care situation)	Rest of the world	SVd Arm	78	27	34,62	51	65,38	NA	8,28	NA	2,56	1,32	4,98	0,0043	0,9891
Patients with at least one AESI or AECI Weight Decreased	Region (by medical care situation)	Rest of the world	Vd Arm	68	14	20,59	54	79,41	NA	NA	NA	-	-	-	-	0,9891
Patients with at least one AESI or AECI Weight Decreased	Race	Races other than White	SVd Arm	34	14	41,18	20	58,82	8,28	4,04	NA	2,91	1,15	7,36	0,0184	0,8514
Patients with at least one AESI or AECI Weight Decreased	Race	Races other than White	Vd Arm	42	9	21,43	33	78,57	NA	NA	NA	-	-	-	-	0,8514
Patients with at least one AESI or AECI Weight Decreased	Race	White	SVd Arm	161	37	22,98	124	77,02	NA	NA	NA	2,62	1,44	4,77	0,0011	0,8514
Patients with at least one AESI or AECI Weight Decreased	Race	White	Vd Arm	162	16	9,88	146	90,12	NA	NA	NA	-	-	-	-	0,8514
Patients with at least one AESI or AECI Weight Decreased	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Weight Decreased	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Weight Decreased	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	42	24,56	129	75,44	NA	NA	NA	2,33	1,39	3,90	0,0010	NA
Patients with at least one AESI or AECI Weight Decreased	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	23	12,43	162	87,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Weight Decreased	Prior PI therapies	N	SVd Arm	48	10	20,83	38	79,17	NA	NA	NA	2,33	0,79	6,86	0,1156	0,8733
Patients with at least one AESI or AECI Weight Decreased	Prior PI therapies	N	Vd Arm	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,8733
Patients with at least one AESI or AECI Weight Decreased	Prior PI therapies	Y	SVd Arm	147	41	27,89	106	72,11	NA	NA	NA	2,57	1,50	4,41	0,0004	0,8733
Patients with at least one AESI or AECI Weight Decreased	Prior PI therapies	Y	Vd Arm	157	20	12,74	137	87,26	NA	NA	NA	-	-	-	-	0,8733
Patients with at least one AESI or AECI Weight Decreased	Prior anti-MM regimen	>1	SVd Arm	98	27	27,55	71	72,45	NA	NA	NA	2,74	1,40	5,36	0,0023	0,7208
Patients with at least one AESI or AECI Weight Decreased	Prior anti-MM regimen	>1	Vd Arm	104	13	12,50	91	87,50	NA	NA	NA	-	-	-	-	0,7208
Patients with at least one AESI or AECI Weight Decreased	Prior anti-MM regimen	1	SVd Arm	97	24	24,74	73	75,26	NA	NA	NA	2,30	1,14	4,60	0,0161	0,7208
Patients with at least one AESI or AECI Weight Decreased	Prior anti-MM regimen	1	Vd Arm	100	12	12,00	88	88,00	NA	NA	NA	-	-	-	-	0,7208
Patients with at least one AESI or AECI Weight Decreased	Baseline single cytogenetic alterations	N	SVd Arm	98	26	26,53	72	73,47	NA	NA	NA	2,44	1,29	4,61	0,0047	0,8655
Patients with at least one AESI or AECI Weight Decreased	Baseline single cytogenetic alterations	N	Vd Arm	111	16	14,41	95	85,59	NA	NA	NA	-	-	-	-	0,8655
Patients with at least one AESI or AECI Weight Decreased	Baseline single cytogenetic alterations	Y	SVd Arm	97	25	25,77	72	74,23	NA	NA	NA	2,66	1,24	5,70	0,0091	0,8655
Patients with at least one AESI or AECI Weight Decreased	Baseline single cytogenetic alterations	Y	Vd Arm	93	9	9,68	84	90,32	NA	NA	NA	-	-	-	-	0,8655
Patients with at least one AESI or AECI Weight Decreased	Previously Exposed to Bortezomib	N	SVd Arm	61	13	21,31	48	78,69	NA	NA	NA	1,47	0,60	3,57	0,3933	0,1707
Patients with at least one AESI or AECI Weight Decreased	Previously Exposed to Bortezomib	N	Vd Arm	62	9	14,52	53	85,48	NA	NA	NA	-	-	-	-	0,1707
Patients with at least one AESI or AECI Weight Decreased	Previously Exposed to Bortezomib	Y	SVd Arm	134	38	28,36	96	71,64	NA	NA	NA	3,10	1,71	5,60	0,0001	0,1707

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Weight Decreased	Previously Exposed to Bortezomib	Y	Vd Arm	142	16	11,27	126	88,73	NA	NA	NA	-	-	-	-	0,1707
Patients with at least one AESI or AECI Pneumonia	total	-	SVd Arm	195	37	18,97	158	81,03	NA	NA	NA	1,13	0,71	1,80	0,6104	NA
Patients with at least one AESI or AECI Pneumonia	total	-	Vd Arm	204	35	17,16	169	82,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Pneumonia	Gender	Female	SVd Arm	80	17	21,25	63	78,75	NA	34,50	NA	1,97	0,92	4,21	0,0748	0,1199
Patients with at least one AESI or AECI Pneumonia	Gender	Female	Vd Arm	91	14	15,38	77	84,62	NA	NA	NA	-	-	-	-	0,1199
Patients with at least one AESI or AECI Pneumonia	Gender	Male	SVd Arm	115	20	17,39	95	82,61	NA	NA	NA	0,91	0,49	1,68	0,7575	0,1199
Patients with at least one AESI or AECI Pneumonia	Gender	Male	Vd Arm	113	21	18,58	92	81,42	NA	NA	NA	-	-	-	-	0,1199
Patients with at least one AESI or AECI Pneumonia	Age Group	<65	SVd Arm	86	19	22,09	67	77,91	NA	34,50	NA	1,29	0,62	2,67	0,4906	0,6171
Patients with at least one AESI or AECI Pneumonia	Age Group	<65	Vd Arm	75	13	17,33	62	82,67	NA	NA	NA	-	-	-	-	0,6171
Patients with at least one AESI or AECI Pneumonia	Age Group	>=65	SVd Arm	109	18	16,51	91	83,49	NA	NA	NA	1,01	0,54	1,90	0,9751	0,6171
Patients with at least one AESI or AECI Pneumonia	Age Group	>=65	Vd Arm	129	22	17,05	107	82,95	NA	NA	NA	-	-	-	-	0,6171
Patients with at least one AESI or AECI Pneumonia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	32	18,50	141	81,50	NA	NA	NA	1,03	0,63	1,71	0,8934	0,2377
Patients with at least one AESI or AECI Pneumonia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	30	17,24	144	82,76	NA	NA	NA	-	-	-	-	0,2377
Patients with at least one AESI or AECI Pneumonia	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	NA	3,06	NA	2,70	0,60	12,22	0,1846	0,2377
Patients with at least one AESI or AECI Pneumonia	Baseline R-ISS stage	Stage III	Vd Arm	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,2377
Patients with at least one AESI or AECI Pneumonia	Baseline ISS stage	Stage I or II	SVd Arm	163	23	14,11	140	85,89	NA	NA	NA	0,80	0,46	1,38	0,4191	0,0241
Patients with at least one AESI or AECI Pneumonia	Baseline ISS stage	Stage I or II	Vd Arm	173	29	16,76	144	83,24	NA	NA	NA	-	-	-	-	0,0241
Patients with at least one AESI or AECI Pneumonia	Baseline ISS stage	Stage III	SVd Arm	32	14	43,75	18	56,25	12,55	6,80	NA	2,88	1,09	7,63	0,0259	0,0241
Patients with at least one AESI or AECI Pneumonia	Baseline ISS stage	Stage III	Vd Arm	31	6	19,35	25	80,65	20,90	20,90	NA	-	-	-	-	0,0241
Patients with at least one AESI or AECI Pneumonia	Region (SAP)	Region 1	SVd Arm	18	2	11,11	16	88,89	NA	NA	NA	0,28	0,03	2,69	0,2386	0,6512
Patients with at least one AESI or AECI Pneumonia	Region (SAP)	Region 1	Vd Arm	17	3	17,65	14	82,35	NA	NA	NA	-	-	-	-	0,6512
Patients with at least one AESI or AECI Pneumonia	Region (SAP)	Region 2	SVd Arm	61	11	18,03	50	81,97	34,50	12,75	NA	1,21	0,47	3,12	0,6933	0,6512
Patients with at least one AESI or AECI Pneumonia	Region (SAP)	Region 2	Vd Arm	64	8	12,50	56	87,50	NA	NA	NA	-	-	-	-	0,6512
Patients with at least one AESI or AECI Pneumonia	Region (SAP)	Region 3	SVd Arm	47	7	14,89	40	85,11	NA	NA	NA	0,83	0,28	2,47	0,7405	0,6512
Patients with at least one AESI or AECI Pneumonia	Region (SAP)	Region 3	Vd Arm	53	8	15,09	45	84,91	NA	NA	NA	-	-	-	-	0,6512
Patients with at least one AESI or AECI Pneumonia	Region (SAP)	Region 4	SVd Arm	69	17	24,64	52	75,36	NA	NA	NA	1,15	0,58	2,29	0,6828	0,6512
Patients with at least one AESI or AECI Pneumonia	Region (SAP)	Region 4	Vd Arm	70	16	22,86	54	77,14	NA	NA	NA	-	-	-	-	0,6512
Patients with at least one AESI or AECI Pneumonia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	16	13,68	101	86,32	NA	NA	NA	0,90	0,45	1,77	0,7528	0,5256
Patients with at least one AESI or AECI Pneumonia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	19	13,97	117	86,03	NA	NA	NA	-	-	-	-	0,5256
Patients with at least one AESI or AECI Pneumonia	Region (by medical care situation)	Rest of the world	SVd Arm	78	21	26,92	57	73,08	NA	NA	NA	1,22	0,63	2,35	0,5564	0,5256

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Pneumonia	Region (by medical care situation)	Rest of the world	Vd Arm	68	16	23,53	52	76,47	NA	NA	NA	-	-	-	-	0,5256
Patients with at least one AESI or AECI Pneumonia	Race	Races other than White	SVd Arm	34	7	20,59	27	79,41	NA	NA	NA	1,58	0,50	4,99	0,4314	0,5307
Patients with at least one AESI or AECI Pneumonia	Race	Races other than White	Vd Arm	42	6	14,29	36	85,71	NA	NA	NA	-	-	-	-	0,5307
Patients with at least one AESI or AECI Pneumonia	Race	White	SVd Arm	161	30	18,63	131	81,37	NA	NA	NA	1,06	0,63	1,78	0,8367	0,5307
Patients with at least one AESI or AECI Pneumonia	Race	White	Vd Arm	162	29	17,90	133	82,10	NA	NA	NA	-	-	-	-	0,5307
Patients with at least one AESI or AECI Pneumonia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Pneumonia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Pneumonia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	32	18,71	139	81,29	NA	NA	NA	1,07	0,65	1,74	0,7987	NA
Patients with at least one AESI or AECI Pneumonia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	33	17,84	152	82,16	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Pneumonia	Prior PI therapies	N	SVd Arm	48	7	14,58	41	85,42	NA	NA	NA	0,75	0,28	2,04	0,5716	0,3633
Patients with at least one AESI or AECI Pneumonia	Prior PI therapies	N	Vd Arm	47	9	19,15	38	80,85	NA	NA	NA	-	-	-	-	0,3633
Patients with at least one AESI or AECI Pneumonia	Prior PI therapies	Y	SVd Arm	147	30	20,41	117	79,59	NA	34,50	NA	1,27	0,75	2,15	0,3793	0,3633
Patients with at least one AESI or AECI Pneumonia	Prior PI therapies	Y	Vd Arm	157	26	16,56	131	83,44	NA	NA	NA	-	-	-	-	0,3633
Patients with at least one AESI or AECI Pneumonia	Prior anti-MM regimen	>1	SVd Arm	98	20	20,41	78	79,59	NA	34,50	NA	1,32	0,69	2,53	0,4057	0,5044
Patients with at least one AESI or AECI Pneumonia	Prior anti-MM regimen	>1	Vd Arm	104	17	16,35	87	83,65	NA	NA	NA	-	-	-	-	0,5044
Patients with at least one AESI or AECI Pneumonia	Prior anti-MM regimen	1	SVd Arm	97	17	17,53	80	82,47	NA	NA	NA	0,96	0,49	1,87	0,9010	0,5044
Patients with at least one AESI or AECI Pneumonia	Prior anti-MM regimen	1	Vd Arm	100	18	18,00	82	82,00	NA	NA	NA	-	-	-	-	0,5044
Patients with at least one AESI or AECI Pneumonia	Baseline single cytogenetic alterations	N	SVd Arm	98	15	15,31	83	84,69	NA	NA	NA	0,93	0,47	1,84	0,8301	0,4326
Patients with at least one AESI or AECI Pneumonia	Baseline single cytogenetic alterations	N	Vd Arm	111	19	17,12	92	82,88	NA	NA	NA	-	-	-	-	0,4326
Patients with at least one AESI or AECI Pneumonia	Baseline single cytogenetic alterations	Y	SVd Arm	97	22	22,68	75	77,32	NA	NA	NA	1,36	0,69	2,68	0,3669	0,4326
Patients with at least one AESI or AECI Pneumonia	Baseline single cytogenetic alterations	Y	Vd Arm	93	16	17,20	77	82,80	NA	NA	NA	-	-	-	-	0,4326
Patients with at least one AESI or AECI Pneumonia	Previously Exposed to Bortezomib	N	SVd Arm	61	9	14,75	52	85,25	NA	34,50	NA	0,75	0,28	2,04	0,5716	0,4326
Patients with at least one AESI or AECI Pneumonia	Previously Exposed to Bortezomib	N	Vd Arm	62	9	14,52	53	85,48	NA	NA	NA	-	-	-	-	0,4326
Patients with at least one AESI or AECI Pneumonia	Previously Exposed to Bortezomib	Y	SVd Arm	134	28	20,90	106	79,10	NA	NA	NA	1,18	0,69	2,03	0,5430	0,4326
Patients with at least one AESI or AECI Pneumonia	Previously Exposed to Bortezomib	Y	Vd Arm	142	26	18,31	116	81,69	NA	NA	NA	-	-	-	-	0,4326
Patients with at least one AESI or AECI Sepsis	total	-	SVd Arm	195	8	4,10	187	95,90	NA	NA	NA	4,14	0,87	19,68	0,0530	NA
Patients with at least one AESI or AECI Sepsis	total	-	Vd Arm	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Gender	Female	SVd Arm	80	6	7,50	74	92,50	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Gender	Female	Vd Arm	91	1	1,10	90	98,90	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Sepsis	Gender	Male	SVd Arm	115	2	1,74	113	98,26	NA	NA	NA	2,09	0,19	23,10	0,5383	NA
Patients with at least one AESI or AECI Sepsis	Gender	Male	Vd Arm	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Age Group	<65	SVd Arm	86	4	4,65	82	95,35	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Age Group	>=65	SVd Arm	109	4	3,67	105	96,33	NA	NA	NA	2,50	0,44	14,10	0,2832	NA
Patients with at least one AESI or AECI Sepsis	Age Group	>=65	Vd Arm	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Baseline R-ISS stage	Stage I or II	SVd Arm	173	7	4,05	166	95,95	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	NA	NA	NA	1,22	0,06	25,98	0,8964	NA
Patients with at least one AESI or AECI Sepsis	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Baseline ISS stage	Stage I or II	SVd Arm	163	6	3,68	157	96,32	NA	NA	NA	6,03	0,72	50,10	0,0582	0,5331
Patients with at least one AESI or AECI Sepsis	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	0,5331
Patients with at least one AESI or AECI Sepsis	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	NA	NA	NA	2,17	0,20	24,15	0,5174	0,5331
Patients with at least one AESI or AECI Sepsis	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,5331
Patients with at least one AESI or AECI Sepsis	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AESI or AECI Sepsis	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Region (SAP)	Region 2	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	0,89	0,12	6,51	0,9099	NA
Patients with at least one AESI or AECI Sepsis	Region (SAP)	Region 2	Vd Arm	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Region (SAP)	Region 3	SVd Arm	47	1	2,13	46	97,87	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Region (SAP)	Region 4	SVd Arm	69	5	7,25	64	92,75	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	3	2,56	114	97,44	NA	NA	NA	1,83	0,30	11,22	0,5058	NA
Patients with at least one AESI or AECI Sepsis	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Region (by medical care situation)	Rest of the world	SVd Arm	78	5	6,41	73	93,59	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Race	Races other than White	SVd Arm	34	5	14,71	29	85,29	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Race	White	SVd Arm	161	3	1,86	158	98,14	NA	NA	NA	1,66	0,26	10,38	0,5856	NA
Patients with at least one AESI or AECI Sepsis	Race	White	Vd Arm	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Sepsis	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AESI or AECI Sepsis	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	7	4,09	164	95,91	NA	NA	NA	4,11	0,82	20,69	0,0661	NA
Patients with at least one AESI or AECI Sepsis	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	NA	NA	NA	1,31	0,08	22,28	0,8518	0,3637
Patients with at least one AESI or AECI Sepsis	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,3637
Patients with at least one AESI or AECI Sepsis	Prior PI therapies	Y	SVd Arm	147	7	4,76	140	95,24	NA	NA	NA	6,71	0,82	54,57	0,0394	0,3637
Patients with at least one AESI or AECI Sepsis	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,3637
Patients with at least one AESI or AECI Sepsis	Prior anti-MM regimen	>1	SVd Arm	98	7	7,14	91	92,86	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Prior anti-MM regimen	1	SVd Arm	97	1	1,03	96	98,97	NA	NA	NA	0,64	0,06	7,19	0,7123	NA
Patients with at least one AESI or AECI Sepsis	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Baseline single cytogenetic alterations	N	SVd Arm	98	6	6,12	92	93,88	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Baseline single cytogenetic alterations	Y	SVd Arm	97	2	2,06	95	97,94	NA	NA	NA	1,50	0,13	16,79	0,7390	NA
Patients with at least one AESI or AECI Sepsis	Baseline single cytogenetic alterations	Y	Vd Arm	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	NA	NA	NA	0,89	0,07	10,91	0,9280	NA
Patients with at least one AESI or AECI Sepsis	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Previously Exposed to Bortezomib	Y	SVd Arm	134	7	5,22	127	94,78	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Sepsis	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Opportunistic Infection	total	-	SVd Arm	195	16	8,21	179	91,79	NA	NA	NA	1,83	0,81	4,15	0,1425	NA
Patients with at least one AESI or AECI Opportunistic Infection	total	-	Vd Arm	204	9	4,41	195	95,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Opportunistic Infection	Gender	Female	SVd Arm	80	7	8,75	73	91,25	NA	NA	NA	4,20	0,87	20,42	0,0533	0,2089
Patients with at least one AESI or AECI Opportunistic Infection	Gender	Female	Vd Arm	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,2089
Patients with at least one AESI or AECI Opportunistic Infection	Gender	Male	SVd Arm	115	9	7,83	106	92,17	NA	NA	NA	1,27	0,47	3,45	0,6424	0,2089
Patients with at least one AESI or AECI Opportunistic Infection	Gender	Male	Vd Arm	113	7	6,19	106	93,81	NA	NA	NA	-	-	-	-	0,2089
Patients with at least one AESI or AECI Opportunistic Infection	Age Group	<65	SVd Arm	86	9	10,47	77	89,53	NA	NA	NA	1,53	0,47	5,05	0,4777	0,8788
Patients with at least one AESI or AECI Opportunistic Infection	Age Group	<65	Vd Arm	75	4	5,33	71	94,67	NA	NA	NA	-	-	-	-	0,8788
Patients with at least one AESI or AECI Opportunistic Infection	Age Group	>=65	SVd Arm	109	7	6,42	102	93,58	NA	NA	NA	1,75	0,55	5,60	0,3420	0,8788

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Opportunistic Infection	Age Group	>=65	Vd Arm	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,8788
Patients with at least one AESI or AECI Opportunistic Infection	Baseline R-ISS stage	Stage I or II	SVd Arm	173	14	8,09	159	91,91	NA	NA	NA	1,76	0,73	4,20	0,1999	NA
Patients with at least one AESI or AECI Opportunistic Infection	Baseline R-ISS stage	Stage I or II	Vd Arm	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Opportunistic Infection	Baseline R-ISS stage	Stage III	SVd Arm	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Opportunistic Infection	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Opportunistic Infection	Baseline ISS stage	Stage I or II	SVd Arm	163	14	8,59	149	91,41	NA	NA	NA	1,86	0,78	4,43	0,1574	0,7923
Patients with at least one AESI or AECI Opportunistic Infection	Baseline ISS stage	Stage I or II	Vd Arm	173	8	4,62	165	95,38	NA	NA	NA	-	-	-	-	0,7923
Patients with at least one AESI or AECI Opportunistic Infection	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	NA	NA	NA	2,63	0,23	30,59	0,4238	0,7923
Patients with at least one AESI or AECI Opportunistic Infection	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,7923
Patients with at least one AESI or AECI Opportunistic Infection	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,1088
Patients with at least one AESI or AECI Opportunistic Infection	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,1088
Patients with at least one AESI or AECI Opportunistic Infection	Region (SAP)	Region 2	SVd Arm	61	9	14,75	52	85,25	NA	25,23	NA	10,93	1,36	87,92	0,0055	0,1088
Patients with at least one AESI or AECI Opportunistic Infection	Region (SAP)	Region 2	Vd Arm	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,1088
Patients with at least one AESI or AECI Opportunistic Infection	Region (SAP)	Region 3	SVd Arm	47	2	4,26	45	95,74	NA	NA	NA	0,75	0,10	5,42	0,7758	0,1088
Patients with at least one AESI or AECI Opportunistic Infection	Region (SAP)	Region 3	Vd Arm	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,1088
Patients with at least one AESI or AECI Opportunistic Infection	Region (SAP)	Region 4	SVd Arm	69	5	7,25	64	92,75	NA	NA	NA	0,97	0,28	3,35	0,9567	0,1088
Patients with at least one AESI or AECI Opportunistic Infection	Region (SAP)	Region 4	Vd Arm	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,1088
Patients with at least one AESI or AECI Opportunistic Infection	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	9	7,69	108	92,31	NA	NA	NA	2,09	0,69	6,35	0,1832	0,6636
Patients with at least one AESI or AECI Opportunistic Infection	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,6636
Patients with at least one AESI or AECI Opportunistic Infection	Region (by medical care situation)	Rest of the world	SVd Arm	78	7	8,97	71	91,03	NA	NA	NA	1,45	0,42	4,96	0,5536	0,6636
Patients with at least one AESI or AECI Opportunistic Infection	Region (by medical care situation)	Rest of the world	Vd Arm	68	4	5,88	64	94,12	NA	NA	NA	-	-	-	-	0,6636
Patients with at least one AESI or AECI Opportunistic Infection	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	2,40	0,18	31,81	0,4968	0,8082
Patients with at least one AESI or AECI Opportunistic Infection	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,8082
Patients with at least one AESI or AECI Opportunistic Infection	Race	White	SVd Arm	161	14	8,70	147	91,30	NA	NA	NA	1,71	0,71	4,13	0,2244	0,8082
Patients with at least one AESI or AECI Opportunistic Infection	Race	White	Vd Arm	162	8	4,94	154	95,06	NA	NA	NA	-	-	-	-	0,8082
Patients with at least one AESI or AECI Opportunistic Infection	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Opportunistic Infection	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Opportunistic Infection	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	12	7,02	159	92,98	NA	NA	NA	1,39	0,58	3,31	0,4553	NA
Patients with at least one AESI or AECI Opportunistic Infection	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	9	4,86	176	95,14	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Opportunistic Infection	Prior PI therapies	N	SVd Arm	48	3	6,25	45	93,75	NA	NA	NA	0,68	0,15	3,05	0,6136	0,1270
Patients with at least one AESI or AECI Opportunistic Infection	Prior PI therapies	N	Vd Arm	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,1270
Patients with at least one AESI or AECI Opportunistic Infection	Prior PI therapies	Y	SVd Arm	147	13	8,84	134	91,16	NA	NA	NA	2,81	1,00	7,92	0,0408	0,1270
Patients with at least one AESI or AECI Opportunistic Infection	Prior PI therapies	Y	Vd Arm	157	5	3,18	152	96,82	NA	NA	NA	-	-	-	-	0,1270
Patients with at least one AESI or AECI Opportunistic Infection	Prior anti-MM regimen	>1	SVd Arm	98	6	6,12	92	93,88	NA	NA	NA	0,96	0,31	2,98	0,9426	0,1264
Patients with at least one AESI or AECI Opportunistic Infection	Prior anti-MM regimen	>1	Vd Arm	104	6	5,77	98	94,23	NA	NA	NA	-	-	-	-	0,1264
Patients with at least one AESI or AECI Opportunistic Infection	Prior anti-MM regimen	1	SVd Arm	97	10	10,31	87	89,69	NA	NA	NA	3,67	1,01	13,41	0,0351	0,1264
Patients with at least one AESI or AECI Opportunistic Infection	Prior anti-MM regimen	1	Vd Arm	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,1264
Patients with at least one AESI or AECI Opportunistic Infection	Baseline single cytogenetic alterations	N	SVd Arm	98	6	6,12	92	93,88	NA	NA	NA	1,87	0,51	6,82	0,3388	0,9864
Patients with at least one AESI or AECI Opportunistic Infection	Baseline single cytogenetic alterations	N	Vd Arm	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,9864
Patients with at least one AESI or AECI Opportunistic Infection	Baseline single cytogenetic alterations	Y	SVd Arm	97	10	10,31	87	89,69	NA	NA	NA	1,84	0,63	5,40	0,2608	0,9864
Patients with at least one AESI or AECI Opportunistic Infection	Baseline single cytogenetic alterations	Y	Vd Arm	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,9864
Patients with at least one AESI or AECI Opportunistic Infection	Previously Exposed to Bortezomib	N	SVd Arm	61	4	6,56	57	93,44	NA	NA	NA	0,86	0,23	3,25	0,8217	0,1321
Patients with at least one AESI or AECI Opportunistic Infection	Previously Exposed to Bortezomib	N	Vd Arm	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,1321
Patients with at least one AESI or AECI Opportunistic Infection	Previously Exposed to Bortezomib	Y	SVd Arm	134	12	8,96	122	91,04	NA	NA	NA	3,29	1,06	10,27	0,0296	0,1321
Patients with at least one AESI or AECI Opportunistic Infection	Previously Exposed to Bortezomib	Y	Vd Arm	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,1321
Patients with at least one AESI or AECI Blurred Vision	total	-	SVd Arm	195	27	13,85	168	86,15	NA	NA	NA	1,96	1,04	3,70	0,0351	NA
Patients with at least one AESI or AECI Blurred Vision	total	-	Vd Arm	204	15	7,35	189	92,65	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Blurred Vision	Gender	Female	SVd Arm	80	9	11,25	71	88,75	NA	NA	NA	1,20	0,41	3,50	0,7446	0,3325
Patients with at least one AESI or AECI Blurred Vision	Gender	Female	Vd Arm	91	6	6,59	85	93,41	NA	NA	NA	-	-	-	-	0,3325
Patients with at least one AESI or AECI Blurred Vision	Gender	Male	SVd Arm	115	18	15,65	97	84,35	NA	NA	NA	2,33	1,03	5,29	0,0377	0,3325
Patients with at least one AESI or AECI Blurred Vision	Gender	Male	Vd Arm	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	0,3325
Patients with at least one AESI or AECI Blurred Vision	Age Group	<65	SVd Arm	86	11	12,79	75	87,21	NA	NA	NA	0,84	0,34	2,06	0,6958	0,0360
Patients with at least one AESI or AECI Blurred Vision	Age Group	<65	Vd Arm	75	9	12,00	66	88,00	NA	NA	NA	-	-	-	-	0,0360
Patients with at least one AESI or AECI Blurred Vision	Age Group	>=65	SVd Arm	109	16	14,68	93	85,32	NA	NA	NA	3,39	1,31	8,76	0,0075	0,0360
Patients with at least one AESI or AECI Blurred Vision	Age Group	>=65	Vd Arm	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	0,0360
Patients with at least one AESI or AECI Blurred Vision	Baseline R-ISS stage	Stage I or II	SVd Arm	173	25	14,45	148	85,55	NA	NA	NA	2,31	1,13	4,72	0,0179	0,5162
Patients with at least one AESI or AECI Blurred Vision	Baseline R-ISS stage	Stage I or II	Vd Arm	174	11	6,32	163	93,68	NA	NA	NA	-	-	-	-	0,5162
Patients with at least one AESI or AECI Blurred Vision	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	NA	NA	NA	0,87	0,05	15,38	0,9219	0,5162
Patients with at least one AESI or AECI Blurred Vision	Baseline R-ISS stage	Stage III	Vd Arm	16	2	12,50	14	87,50	NA	19,12	NA	-	-	-	-	0,5162

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Blurred Vision	Baseline ISS stage	Stage I or II	SVd Arm	163	25	15,34	138	84,66	NA	NA	NA	2,21	1,11	4,41	0,0206	0,4737
Patients with at least one AESI or AECI Blurred Vision	Baseline ISS stage	Stage I or II	Vd Arm	173	12	6,94	161	93,06	NA	NA	NA	-	-	-	-	0,4737
Patients with at least one AESI or AECI Blurred Vision	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	NA	NA	NA	1,03	0,15	7,36	0,9729	0,4737
Patients with at least one AESI or AECI Blurred Vision	Baseline ISS stage	Stage III	Vd Arm	31	3	9,68	28	90,32	NA	19,12	NA	-	-	-	-	0,4737
Patients with at least one AESI or AECI Blurred Vision	Region (SAP)	Region 1	SVd Arm	18	5	27,78	13	72,22	30,03	NA	NA	2,46	0,42	14,26	0,3033	0,5048
Patients with at least one AESI or AECI Blurred Vision	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,5048
Patients with at least one AESI or AECI Blurred Vision	Region (SAP)	Region 2	SVd Arm	61	12	19,67	49	80,33	NA	NA	NA	2,16	0,81	5,79	0,1150	0,5048
Patients with at least one AESI or AECI Blurred Vision	Region (SAP)	Region 2	Vd Arm	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,5048
Patients with at least one AESI or AECI Blurred Vision	Region (SAP)	Region 3	SVd Arm	47	5	10,64	42	89,36	-	-	-	-	-	-	-	0,5048
Patients with at least one AESI or AECI Blurred Vision	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,5048
Patients with at least one AESI or AECI Blurred Vision	Region (SAP)	Region 4	SVd Arm	69	5	7,25	64	92,75	NA	NA	NA	0,94	0,29	3,04	0,9200	0,5048
Patients with at least one AESI or AECI Blurred Vision	Region (SAP)	Region 4	Vd Arm	70	7	10,00	63	90,00	NA	NA	NA	-	-	-	-	0,5048
Patients with at least one AESI or AECI Blurred Vision	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	20	17,09	97	82,91	NA	NA	NA	2,81	1,23	6,41	0,0104	0,1531
Patients with at least one AESI or AECI Blurred Vision	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	8	5,88	128	94,12	NA	NA	NA	-	-	-	-	0,1531
Patients with at least one AESI or AECI Blurred Vision	Region (by medical care situation)	Rest of the world	SVd Arm	78	7	8,97	71	91,03	NA	NA	NA	1,05	0,36	3,06	0,9324	0,1531
Patients with at least one AESI or AECI Blurred Vision	Region (by medical care situation)	Rest of the world	Vd Arm	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,1531
Patients with at least one AESI or AECI Blurred Vision	Race	Races other than White	SVd Arm	34	3	8,82	31	91,18	NA	NA	NA	1,37	0,29	6,34	0,6888	0,5581
Patients with at least one AESI or AECI Blurred Vision	Race	Races other than White	Vd Arm	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,5581
Patients with at least one AESI or AECI Blurred Vision	Race	White	SVd Arm	161	24	14,91	137	85,09	NA	NA	NA	2,27	1,08	4,78	0,0260	0,5581
Patients with at least one AESI or AECI Blurred Vision	Race	White	Vd Arm	162	10	6,17	152	93,83	NA	NA	NA	-	-	-	-	0,5581
Patients with at least one AESI or AECI Blurred Vision	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AESI or AECI Blurred Vision	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Blurred Vision	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	25	14,62	146	85,38	NA	NA	NA	2,09	1,08	4,06	0,0263	NA
Patients with at least one AESI or AECI Blurred Vision	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	14	7,57	171	92,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Blurred Vision	Prior PI therapies	N	SVd Arm	48	6	12,50	42	87,50	NA	NA	NA	1,88	0,46	7,69	0,3722	0,9489
Patients with at least one AESI or AECI Blurred Vision	Prior PI therapies	N	Vd Arm	47	3	6,38	44	93,62	NA	26,71	NA	-	-	-	-	0,9489
Patients with at least one AESI or AECI Blurred Vision	Prior PI therapies	Y	SVd Arm	147	21	14,29	126	85,71	NA	NA	NA	1,98	0,97	4,04	0,0560	0,9489
Patients with at least one AESI or AECI Blurred Vision	Prior PI therapies	Y	Vd Arm	157	12	7,64	145	92,36	NA	NA	NA	-	-	-	-	0,9489
Patients with at least one AESI or AECI Blurred Vision	Prior anti-MM regimen	>1	SVd Arm	98	9	9,18	89	90,82	NA	NA	NA	0,93	0,38	2,32	0,8844	0,0324

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Blurred Vision	Prior anti-MM regimen	>1	Vd Arm	104	10	9,62	94	90,38	NA	NA	NA	-	-	-	-	0,0324
Patients with at least one AESI or AECI Blurred Vision	Prior anti-MM regimen	1	SVd Arm	97	18	18,56	79	81,44	NA	30,03	NA	4,08	1,50	11,06	0,0029	0,0324
Patients with at least one AESI or AECI Blurred Vision	Prior anti-MM regimen	1	Vd Arm	100	5	5,00	95	95,00	NA	NA	NA	-	-	-	-	0,0324
Patients with at least one AESI or AECI Blurred Vision	Baseline single cytogenetic alterations	N	SVd Arm	98	11	11,22	87	88,78	NA	NA	NA	1,59	0,65	3,93	0,3072	0,4715
Patients with at least one AESI or AECI Blurred Vision	Baseline single cytogenetic alterations	N	Vd Arm	111	9	8,11	102	91,89	NA	NA	NA	-	-	-	-	0,4715
Patients with at least one AESI or AECI Blurred Vision	Baseline single cytogenetic alterations	Y	SVd Arm	97	16	16,49	81	83,51	NA	NA	NA	2,58	1,00	6,62	0,0417	0,4715
Patients with at least one AESI or AECI Blurred Vision	Baseline single cytogenetic alterations	Y	Vd Arm	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,4715
Patients with at least one AESI or AECI Blurred Vision	Previously Exposed to Bortezomib	N	SVd Arm	61	7	11,48	54	88,52	NA	NA	NA	1,83	0,52	6,39	0,3386	0,8577
Patients with at least one AESI or AECI Blurred Vision	Previously Exposed to Bortezomib	N	Vd Arm	62	4	6,45	58	93,55	NA	26,71	NA	-	-	-	-	0,8577
Patients with at least one AESI or AECI Blurred Vision	Previously Exposed to Bortezomib	Y	SVd Arm	134	20	14,93	114	85,07	NA	30,03	NA	2,09	0,99	4,40	0,0482	0,8577
Patients with at least one AESI or AECI Blurred Vision	Previously Exposed to Bortezomib	Y	Vd Arm	142	11	7,75	131	92,25	NA	NA	NA	-	-	-	-	0,8577
Patients with at least one AESI or AECI Cataract	total	-	SVd Arm	195	46	23,59	149	76,41	25,82	16,99	NA	3,06	1,72	5,44	0,0001	NA
Patients with at least one AESI or AECI Cataract	total	-	Vd Arm	204	16	7,84	188	92,16	NA	41,20	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Cataract	Gender	Female	SVd Arm	80	19	23,75	61	76,25	NA	13,83	NA	4,94	1,61	15,13	0,0025	0,2964
Patients with at least one AESI or AECI Cataract	Gender	Female	Vd Arm	91	5	5,49	86	94,51	NA	41,20	NA	-	-	-	-	0,2964
Patients with at least one AESI or AECI Cataract	Gender	Male	SVd Arm	115	27	23,48	88	76,52	25,82	14,85	NA	2,43	1,18	4,99	0,0130	0,2964
Patients with at least one AESI or AECI Cataract	Gender	Male	Vd Arm	113	11	9,73	102	90,27	NA	NA	NA	-	-	-	-	0,2964
Patients with at least one AESI or AECI Cataract	Age Group	<65	SVd Arm	86	29	33,72	57	66,28	17,41	12,62	NA	3,60	1,53	8,45	0,0019	0,5283
Patients with at least one AESI or AECI Cataract	Age Group	<65	Vd Arm	75	8	10,67	67	89,33	41,20	41,20	NA	-	-	-	-	0,5283
Patients with at least one AESI or AECI Cataract	Age Group	>=65	SVd Arm	109	17	15,60	92	84,40	NA	NA	NA	2,44	1,04	5,73	0,0353	0,5283
Patients with at least one AESI or AECI Cataract	Age Group	>=65	Vd Arm	129	8	6,20	121	93,80	NA	NA	NA	-	-	-	-	0,5283
Patients with at least one AESI or AECI Cataract	Baseline R-ISS stage	Stage I or II	SVd Arm	173	40	23,12	133	76,88	26,91	17,41	NA	2,73	1,47	5,04	0,0009	NA
Patients with at least one AESI or AECI Cataract	Baseline R-ISS stage	Stage I or II	Vd Arm	174	14	8,05	160	91,95	41,20	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Cataract	Baseline R-ISS stage	Stage III	SVd Arm	12	3	25,00	9	75,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cataract	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cataract	Baseline ISS stage	Stage I or II	SVd Arm	163	40	24,54	123	75,46	25,82	16,99	NA	2,85	1,57	5,19	0,0003	0,3700
Patients with at least one AESI or AECI Cataract	Baseline ISS stage	Stage I or II	Vd Arm	173	15	8,67	158	91,33	NA	41,20	NA	-	-	-	-	0,3700
Patients with at least one AESI or AECI Cataract	Baseline ISS stage	Stage III	SVd Arm	32	6	18,75	26	81,25	26,91	8,90	NA	7,97	0,92	69,31	0,0269	0,3700
Patients with at least one AESI or AECI Cataract	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,3700
Patients with at least one AESI or AECI Cataract	Region (SAP)	Region 1	SVd Arm	18	5	27,78	13	72,22	20,21	12,78	NA	3,18	0,32	32,14	0,3035	0,9875

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Cataract	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,9875
Patients with at least one AESI or AECI Cataract	Region (SAP)	Region 2	SVd Arm	61	12	19,67	49	80,33	NA	10,64	NA	2,97	1,09	8,08	0,0262	0,9875
Patients with at least one AESI or AECI Cataract	Region (SAP)	Region 2	Vd Arm	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,9875
Patients with at least one AESI or AECI Cataract	Region (SAP)	Region 3	SVd Arm	47	8	17,02	39	82,98	-	-	-	-	-	-	-	0,9875
Patients with at least one AESI or AECI Cataract	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,9875
Patients with at least one AESI or AECI Cataract	Region (SAP)	Region 4	SVd Arm	69	21	30,43	48	69,57	17,41	12,62	NA	3,31	1,38	7,90	0,0045	0,9875
Patients with at least one AESI or AECI Cataract	Region (SAP)	Region 4	Vd Arm	70	8	11,43	62	88,57	41,20	NA	NA	-	-	-	-	0,9875
Patients with at least one AESI or AECI Cataract	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	20	17,09	97	82,91	NA	20,30	NA	2,93	1,23	7,00	0,0112	0,7301
Patients with at least one AESI or AECI Cataract	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	7	5,15	129	94,85	NA	NA	NA	-	-	-	-	0,7301
Patients with at least one AESI or AECI Cataract	Region (by medical care situation)	Rest of the world	SVd Arm	78	26	33,33	52	66,67	14,85	10,51	NA	3,61	1,61	8,10	0,0009	0,7301
Patients with at least one AESI or AECI Cataract	Region (by medical care situation)	Rest of the world	Vd Arm	68	9	13,24	59	86,76	41,20	NA	NA	-	-	-	-	0,7301
Patients with at least one AESI or AECI Cataract	Race	Races other than White	SVd Arm	34	10	29,41	24	70,59	NA	7,29	NA	3,62	0,90	14,50	0,0557	0,7396
Patients with at least one AESI or AECI Cataract	Race	Races other than White	Vd Arm	42	5	11,90	37	88,10	NA	23,13	NA	-	-	-	-	0,7396
Patients with at least one AESI or AECI Cataract	Race	White	SVd Arm	161	36	22,36	125	77,64	25,82	16,99	NA	2,78	1,40	5,53	0,0023	0,7396
Patients with at least one AESI or AECI Cataract	Race	White	Vd Arm	162	11	6,79	151	93,21	NA	41,20	NA	-	-	-	-	0,7396
Patients with at least one AESI or AECI Cataract	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cataract	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cataract	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	40	23,39	131	76,61	26,91	16,99	NA	3,37	1,79	6,36	0,0001	NA
Patients with at least one AESI or AECI Cataract	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	13	7,03	172	92,97	NA	41,20	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Cataract	Prior PI therapies	N	SVd Arm	48	13	27,08	35	72,92	26,91	13,37	NA	1,50	0,58	3,85	0,4007	0,0812
Patients with at least one AESI or AECI Cataract	Prior PI therapies	N	Vd Arm	47	7	14,89	40	85,11	NA	NA	NA	-	-	-	-	0,0812
Patients with at least one AESI or AECI Cataract	Prior PI therapies	Y	SVd Arm	147	33	22,45	114	77,55	25,82	14,85	NA	4,36	2,08	9,15	0,0000	0,0812
Patients with at least one AESI or AECI Cataract	Prior PI therapies	Y	Vd Arm	157	9	5,73	148	94,27	NA	41,20	NA	-	-	-	-	0,0812
Patients with at least one AESI or AECI Cataract	Prior anti-MM regimen	>1	SVd Arm	98	27	27,55	71	72,45	17,41	11,96	NA	3,41	1,59	7,31	0,0008	0,6605
Patients with at least one AESI or AECI Cataract	Prior anti-MM regimen	>1	Vd Arm	104	9	8,65	95	91,35	41,20	NA	NA	-	-	-	-	0,6605
Patients with at least one AESI or AECI Cataract	Prior anti-MM regimen	1	SVd Arm	97	19	19,59	78	80,41	NA	20,21	NA	2,62	1,09	6,31	0,0255	0,6605
Patients with at least one AESI or AECI Cataract	Prior anti-MM regimen	1	Vd Arm	100	7	7,00	93	93,00	NA	NA	NA	-	-	-	-	0,6605
Patients with at least one AESI or AECI Cataract	Baseline single cytogenetic alterations	N	SVd Arm	98	24	24,49	74	75,51	26,91	13,83	NA	2,87	1,34	6,11	0,0045	0,9463
Patients with at least one AESI or AECI Cataract	Baseline single cytogenetic alterations	N	Vd Arm	111	10	9,01	101	90,99	41,20	41,20	NA	-	-	-	-	0,9463

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Cataract	Baseline single cytogenetic alterations	Y	SVd Arm	97	22	22,68	75	77,32	25,82	16,99	NA	2,98	1,20	7,43	0,0139	0,9463
Patients with at least one AESI or AECI Cataract	Baseline single cytogenetic alterations	Y	Vd Arm	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,9463
Patients with at least one AESI or AECI Cataract	Previously Exposed to Bortezomib	N	SVd Arm	61	17	27,87	44	72,13	16,99	12,62	NA	1,77	0,71	4,41	0,2148	0,2028
Patients with at least one AESI or AECI Cataract	Previously Exposed to Bortezomib	N	Vd Arm	62	7	11,29	55	88,71	NA	NA	NA	-	-	-	-	0,2028
Patients with at least one AESI or AECI Cataract	Previously Exposed to Bortezomib	Y	SVd Arm	134	29	21,64	105	78,36	25,82	17,41	NA	3,82	1,80	8,11	0,0002	0,2028
Patients with at least one AESI or AECI Cataract	Previously Exposed to Bortezomib	Y	Vd Arm	142	9	6,34	133	93,66	41,20	41,20	NA	-	-	-	-	0,2028
Patients with at least one AESI or AECI Hyponatraemia	total	-	SVd Arm	195	16	8,21	179	91,79	NA	NA	NA	5,95	1,73	20,44	0,0013	NA
Patients with at least one AESI or AECI Hyponatraemia	total	-	Vd Arm	204	3	1,47	201	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Gender	Female	SVd Arm	80	9	11,25	71	88,75	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Gender	Male	SVd Arm	115	7	6,09	108	93,91	NA	NA	NA	2,33	0,60	9,05	0,2088	NA
Patients with at least one AESI or AECI Hyponatraemia	Gender	Male	Vd Arm	113	3	2,65	110	97,35	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Age Group	<65	SVd Arm	86	8	9,30	78	90,70	NA	NA	NA	3,37	0,70	16,18	0,1090	0,4513
Patients with at least one AESI or AECI Hyponatraemia	Age Group	<65	Vd Arm	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,4513
Patients with at least one AESI or AECI Hyponatraemia	Age Group	>=65	SVd Arm	109	8	7,34	101	92,66	NA	NA	NA	9,18	1,14	73,87	0,0116	0,4513
Patients with at least one AESI or AECI Hyponatraemia	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	0,4513
Patients with at least one AESI or AECI Hyponatraemia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	12	6,94	161	93,06	NA	NA	NA	4,24	1,19	15,05	0,0151	NA
Patients with at least one AESI or AECI Hyponatraemia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Baseline R-ISS stage	Stage III	SVd Arm	12	3	25,00	9	75,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Baseline ISS stage	Stage I or II	SVd Arm	163	10	6,13	153	93,87	NA	NA	NA	3,58	0,98	13,01	0,0387	NA
Patients with at least one AESI or AECI Hyponatraemia	Baseline ISS stage	Stage I or II	Vd Arm	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Baseline ISS stage	Stage III	SVd Arm	32	6	18,75	26	81,25	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,6624
Patients with at least one AESI or AECI Hyponatraemia	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,6624
Patients with at least one AESI or AECI Hyponatraemia	Region (SAP)	Region 2	SVd Arm	61	6	9,84	55	90,16	NA	NA	NA	7,81	0,91	66,69	0,0284	0,6624
Patients with at least one AESI or AECI Hyponatraemia	Region (SAP)	Region 2	Vd Arm	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,6624
Patients with at least one AESI or AECI Hyponatraemia	Region (SAP)	Region 3	SVd Arm	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,6624
Patients with at least one AESI or AECI Hyponatraemia	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,6624

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Hyponatraemia	Region (SAP)	Region 4	SVd Arm	69	8	11,59	61	88,41	NA	NA	NA	4,33	0,92	20,44	0,0435	0,6624
Patients with at least one AESI or AECI Hyponatraemia	Region (SAP)	Region 4	Vd Arm	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,6624
Patients with at least one AESI or AECI Hyponatraemia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	7	5,98	110	94,02	NA	NA	NA	8,57	1,04	70,60	0,0173	0,5602
Patients with at least one AESI or AECI Hyponatraemia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,5602
Patients with at least one AESI or AECI Hyponatraemia	Region (by medical care situation)	Rest of the world	SVd Arm	78	9	11,54	69	88,46	NA	NA	NA	3,95	0,85	18,35	0,0589	0,5602
Patients with at least one AESI or AECI Hyponatraemia	Region (by medical care situation)	Rest of the world	Vd Arm	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,5602
Patients with at least one AESI or AECI Hyponatraemia	Race	Races other than White	SVd Arm	34	4	11,76	30	88,24	NA	NA	NA	2,47	0,43	14,19	0,2955	0,2210
Patients with at least one AESI or AECI Hyponatraemia	Race	Races other than White	Vd Arm	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,2210
Patients with at least one AESI or AECI Hyponatraemia	Race	White	SVd Arm	161	12	7,45	149	92,55	NA	NA	NA	13,26	1,72	102,41	0,0013	0,2210
Patients with at least one AESI or AECI Hyponatraemia	Race	White	Vd Arm	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	0,2210
Patients with at least one AESI or AECI Hyponatraemia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	14	8,19	157	91,81	NA	NA	NA	5,27	1,51	18,38	0,0036	NA
Patients with at least one AESI or AECI Hyponatraemia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	3	1,62	182	98,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Hyponatraemia	Prior PI therapies	N	SVd Arm	48	3	6,25	45	93,75	NA	NA	NA	3,09	0,32	29,76	0,3047	0,5275
Patients with at least one AESI or AECI Hyponatraemia	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,5275
Patients with at least one AESI or AECI Hyponatraemia	Prior PI therapies	Y	SVd Arm	147	13	8,84	134	91,16	NA	NA	NA	7,40	1,67	32,86	0,0020	0,5275
Patients with at least one AESI or AECI Hyponatraemia	Prior PI therapies	Y	Vd Arm	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,5275
Patients with at least one AESI or AECI Hyponatraemia	Prior anti-MM regimen	>1	SVd Arm	98	7	7,14	91	92,86	NA	NA	NA	3,79	0,79	18,27	0,0744	0,4504
Patients with at least one AESI or AECI Hyponatraemia	Prior anti-MM regimen	>1	Vd Arm	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	0,4504
Patients with at least one AESI or AECI Hyponatraemia	Prior anti-MM regimen	1	SVd Arm	97	9	9,28	88	90,72	NA	NA	NA	10,31	1,30	81,62	0,0062	0,4504
Patients with at least one AESI or AECI Hyponatraemia	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,4504
Patients with at least one AESI or AECI Hyponatraemia	Baseline single cytogenetic alterations	N	SVd Arm	98	7	7,14	91	92,86	NA	NA	NA	4,26	0,88	20,57	0,0493	0,5978
Patients with at least one AESI or AECI Hyponatraemia	Baseline single cytogenetic alterations	N	Vd Arm	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,5978
Patients with at least one AESI or AECI Hyponatraemia	Baseline single cytogenetic alterations	Y	SVd Arm	97	9	9,28	88	90,72	NA	NA	NA	8,58	1,08	67,96	0,0145	0,5978
Patients with at least one AESI or AECI Hyponatraemia	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,5978
Patients with at least one AESI or AECI Hyponatraemia	Previously Exposed to Bortezomib	N	SVd Arm	61	3	4,92	58	95,08	NA	NA	NA	3,09	0,32	29,76	0,3047	0,5318
Patients with at least one AESI or AECI Hyponatraemia	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,5318
Patients with at least one AESI or AECI Hyponatraemia	Previously Exposed to Bortezomib	Y	SVd Arm	134	13	9,70	121	90,30	NA	NA	NA	7,33	1,65	32,61	0,0022	0,5318

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Hyponatraemia	Previously Exposed to Bortezomib	Y	Vd Arm	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,5318
Patients with at least one AESI or AECI Neurological Toxicity	total	-	SVd Arm	195	48	24,62	147	75,38	NA	NA	NA	3,03	1,74	5,29	0,0000	NA
Patients with at least one AESI or AECI Neurological Toxicity	total	-	Vd Arm	204	17	8,33	187	91,67	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Neurological Toxicity	Gender	Female	SVd Arm	80	20	25,00	60	75,00	NA	NA	NA	3,51	1,40	8,85	0,0046	0,6773
Patients with at least one AESI or AECI Neurological Toxicity	Gender	Female	Vd Arm	91	6	6,59	85	93,41	NA	NA	NA	-	-	-	-	0,6773
Patients with at least one AESI or AECI Neurological Toxicity	Gender	Male	SVd Arm	115	28	24,35	87	75,65	NA	NA	NA	2,74	1,35	5,59	0,0038	0,6773
Patients with at least one AESI or AECI Neurological Toxicity	Gender	Male	Vd Arm	113	11	9,73	102	90,27	NA	NA	NA	-	-	-	-	0,6773
Patients with at least one AESI or AECI Neurological Toxicity	Age Group	<65	SVd Arm	86	10	11,63	76	88,37	NA	NA	NA	1,62	0,54	4,85	0,3822	0,1269
Patients with at least one AESI or AECI Neurological Toxicity	Age Group	<65	Vd Arm	75	5	6,67	70	93,33	NA	NA	NA	-	-	-	-	0,1269
Patients with at least one AESI or AECI Neurological Toxicity	Age Group	>=65	SVd Arm	109	38	34,86	71	65,14	NA	15,44	NA	4,39	2,27	8,48	0,0000	0,1269
Patients with at least one AESI or AECI Neurological Toxicity	Age Group	>=65	Vd Arm	129	12	9,30	117	90,70	NA	NA	NA	-	-	-	-	0,1269
Patients with at least one AESI or AECI Neurological Toxicity	Baseline R-ISS stage	Stage I or II	SVd Arm	173	42	24,28	131	75,72	NA	NA	NA	3,20	1,75	5,88	0,0001	NA
Patients with at least one AESI or AECI Neurological Toxicity	Baseline R-ISS stage	Stage I or II	Vd Arm	174	14	8,05	160	91,95	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Neurological Toxicity	Baseline R-ISS stage	Stage III	SVd Arm	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Neurological Toxicity	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Neurological Toxicity	Baseline ISS stage	Stage I or II	SVd Arm	163	44	26,99	119	73,01	NA	NA	NA	3,54	1,94	6,47	0,0000	0,2376
Patients with at least one AESI or AECI Neurological Toxicity	Baseline ISS stage	Stage I or II	Vd Arm	173	14	8,09	159	91,91	NA	NA	NA	-	-	-	-	0,2376
Patients with at least one AESI or AECI Neurological Toxicity	Baseline ISS stage	Stage III	SVd Arm	32	4	12,50	28	87,50	NA	NA	NA	1,34	0,30	6,01	0,7050	0,2376
Patients with at least one AESI or AECI Neurological Toxicity	Baseline ISS stage	Stage III	Vd Arm	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,2376
Patients with at least one AESI or AECI Neurological Toxicity	Region (SAP)	Region 1	SVd Arm	18	10	55,56	8	44,44	3,06	0,56	NA	2,46	0,64	9,40	0,1753	0,0506
Patients with at least one AESI or AECI Neurological Toxicity	Region (SAP)	Region 1	Vd Arm	17	4	23,53	13	76,47	21,75	NA	NA	-	-	-	-	0,0506
Patients with at least one AESI or AECI Neurological Toxicity	Region (SAP)	Region 2	SVd Arm	61	27	44,26	34	55,74	15,44	3,71	NA	7,42	2,81	19,61	0,0000	0,0506
Patients with at least one AESI or AECI Neurological Toxicity	Region (SAP)	Region 2	Vd Arm	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,0506
Patients with at least one AESI or AECI Neurological Toxicity	Region (SAP)	Region 3	SVd Arm	47	3	6,38	44	93,62	NA	NA	NA	1,51	0,15	15,59	0,7274	0,0506
Patients with at least one AESI or AECI Neurological Toxicity	Region (SAP)	Region 3	Vd Arm	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,0506
Patients with at least one AESI or AECI Neurological Toxicity	Region (SAP)	Region 4	SVd Arm	69	8	11,59	61	88,41	NA	NA	NA	1,01	0,35	2,89	0,9863	0,0506
Patients with at least one AESI or AECI Neurological Toxicity	Region (SAP)	Region 4	Vd Arm	70	7	10,00	63	90,00	NA	NA	NA	-	-	-	-	0,0506
Patients with at least one AESI or AECI Neurological Toxicity	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	34	29,06	83	70,94	NA	NA	NA	3,48	1,78	6,80	0,0001	0,6176
Patients with at least one AESI or AECI Neurological Toxicity	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	12	8,82	124	91,18	NA	NA	NA	-	-	-	-	0,6176
Patients with at least one AESI or AECI Neurological Toxicity	Region (by medical care situation)	Rest of the world	SVd Arm	78	14	17,95	64	82,05	NA	NA	NA	2,54	0,90	7,17	0,0672	0,6176

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Neurological Toxicity	Region (by medical care situation)	Rest of the world	Vd Arm	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,6176
Patients with at least one AESI or AECI Neurological Toxicity	Race	Races other than White	SVd Arm	34	9	26,47	25	73,53	NA	24,94	NA	2,47	0,75	8,14	0,1277	0,6243
Patients with at least one AESI or AECI Neurological Toxicity	Race	Races other than White	Vd Arm	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,6243
Patients with at least one AESI or AECI Neurological Toxicity	Race	White	SVd Arm	161	39	24,22	122	75,78	NA	NA	NA	3,47	1,81	6,67	0,0001	0,6243
Patients with at least one AESI or AECI Neurological Toxicity	Race	White	Vd Arm	162	12	7,41	150	92,59	NA	NA	NA	-	-	-	-	0,6243
Patients with at least one AESI or AECI Neurological Toxicity	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Neurological Toxicity	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Neurological Toxicity	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	41	23,98	130	76,02	NA	NA	NA	2,69	1,52	4,76	0,0004	NA
Patients with at least one AESI or AECI Neurological Toxicity	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	17	9,19	168	90,81	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Neurological Toxicity	Prior PI therapies	N	SVd Arm	48	13	27,08	35	72,92	NA	NA	NA	3,33	1,08	10,29	0,0266	0,8465
Patients with at least one AESI or AECI Neurological Toxicity	Prior PI therapies	N	Vd Arm	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,8465
Patients with at least one AESI or AECI Neurological Toxicity	Prior PI therapies	Y	SVd Arm	147	35	23,81	112	76,19	NA	NA	NA	2,93	1,54	5,57	0,0006	0,8465
Patients with at least one AESI or AECI Neurological Toxicity	Prior PI therapies	Y	Vd Arm	157	13	8,28	144	91,72	NA	NA	NA	-	-	-	-	0,8465
Patients with at least one AESI or AECI Neurological Toxicity	Prior anti-MM regimen	>1	SVd Arm	98	23	23,47	75	76,53	NA	NA	NA	4,81	1,82	12,71	0,0005	0,2209
Patients with at least one AESI or AECI Neurological Toxicity	Prior anti-MM regimen	>1	Vd Arm	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,2209
Patients with at least one AESI or AECI Neurological Toxicity	Prior anti-MM regimen	1	SVd Arm	97	25	25,77	72	74,23	NA	NA	NA	2,28	1,14	4,56	0,0165	0,2209
Patients with at least one AESI or AECI Neurological Toxicity	Prior anti-MM regimen	1	Vd Arm	100	12	12,00	88	88,00	NA	NA	NA	-	-	-	-	0,2209
Patients with at least one AESI or AECI Neurological Toxicity	Baseline single cytogenetic alterations	N	SVd Arm	98	25	25,51	73	74,49	NA	NA	NA	4,80	2,02	11,41	0,0001	0,1819
Patients with at least one AESI or AECI Neurological Toxicity	Baseline single cytogenetic alterations	N	Vd Arm	111	7	6,31	104	93,69	NA	NA	NA	-	-	-	-	0,1819
Patients with at least one AESI or AECI Neurological Toxicity	Baseline single cytogenetic alterations	Y	SVd Arm	97	23	23,71	74	76,29	NA	NA	NA	2,21	1,05	4,65	0,0330	0,1819
Patients with at least one AESI or AECI Neurological Toxicity	Baseline single cytogenetic alterations	Y	Vd Arm	93	10	10,75	83	89,25	NA	NA	NA	-	-	-	-	0,1819
Patients with at least one AESI or AECI Neurological Toxicity	Previously Exposed to Bortezomib	N	SVd Arm	61	18	29,51	43	70,49	NA	NA	NA	2,99	1,16	7,72	0,0173	0,9485
Patients with at least one AESI or AECI Neurological Toxicity	Previously Exposed to Bortezomib	N	Vd Arm	62	6	9,68	56	90,32	NA	NA	NA	-	-	-	-	0,9485
Patients with at least one AESI or AECI Neurological Toxicity	Previously Exposed to Bortezomib	Y	SVd Arm	134	30	22,39	104	77,61	NA	NA	NA	2,88	1,44	5,78	0,0018	0,9485
Patients with at least one AESI or AECI Neurological Toxicity	Previously Exposed to Bortezomib	Y	Vd Arm	142	11	7,75	131	92,25	NA	NA	NA	-	-	-	-	0,9485
Patients with at least one AESI or AECI Hepatobiliary Disorders	total	-	SVd Arm	195	24	12,31	171	87,69	NA	NA	NA	1,34	0,73	2,48	0,3430	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	total	-	Vd Arm	204	18	8,82	186	91,18	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	Gender	Female	SVd Arm	80	7	8,75	73	91,25	NA	NA	NA	1,04	0,36	3,00	0,9402	0,5955
Patients with at least one AESI or AECI Hepatobiliary Disorders	Gender	Female	Vd Arm	91	7	7,69	84	92,31	NA	NA	NA	-	-	-	-	0,5955

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Hepatobiliary Disorders	Gender	Male	SVd Arm	115	17	14,78	98	85,22	NA	NA	NA	1,48	0,69	3,19	0,3088	0,5955
Patients with at least one AESI or AECI Hepatobiliary Disorders	Gender	Male	Vd Arm	113	11	9,73	102	90,27	NA	NA	NA	-	-	-	-	0,5955
Patients with at least one AESI or AECI Hepatobiliary Disorders	Age Group	<65	SVd Arm	86	12	13,95	74	86,05	NA	NA	NA	1,53	0,59	3,98	0,3766	0,6967
Patients with at least one AESI or AECI Hepatobiliary Disorders	Age Group	<65	Vd Arm	75	7	9,33	68	90,67	NA	NA	NA	-	-	-	-	0,6967
Patients with at least one AESI or AECI Hepatobiliary Disorders	Age Group	>=65	SVd Arm	109	12	11,01	97	88,99	NA	NA	NA	1,19	0,52	2,73	0,6751	0,6967
Patients with at least one AESI or AECI Hepatobiliary Disorders	Age Group	>=65	Vd Arm	129	11	8,53	118	91,47	NA	NA	NA	-	-	-	-	0,6967
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline R-ISS stage	Stage I or II	SVd Arm	173	22	12,72	151	87,28	NA	NA	NA	1,38	0,71	2,66	0,3367	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline R-ISS stage	Stage I or II	Vd Arm	174	15	8,62	159	91,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline R-ISS stage	Stage III	Vd Arm	16	2	12,50	14	87,50	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline ISS stage	Stage I or II	SVd Arm	163	23	14,11	140	85,89	NA	NA	NA	1,96	0,97	3,94	0,0546	0,0269
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline ISS stage	Stage I or II	Vd Arm	173	12	6,94	161	93,06	NA	NA	NA	-	-	-	-	0,0269
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	NA	NA	NA	0,16	0,02	1,31	0,0501	0,0269
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline ISS stage	Stage III	Vd Arm	31	6	19,35	25	80,65	NA	NA	NA	-	-	-	-	0,0269
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,3367
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,3367
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (SAP)	Region 2	SVd Arm	61	7	11,48	54	88,52	NA	NA	NA	0,83	0,26	2,62	0,7522	0,3367
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (SAP)	Region 2	Vd Arm	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,3367
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (SAP)	Region 3	SVd Arm	47	5	10,64	42	89,36	NA	NA	NA	0,58	0,18	1,88	0,3613	0,3367
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (SAP)	Region 3	Vd Arm	53	7	13,21	46	86,79	NA	NA	NA	-	-	-	-	0,3367
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (SAP)	Region 4	SVd Arm	69	9	13,04	60	86,96	NA	NA	NA	1,88	0,63	5,62	0,2536	0,3367
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (SAP)	Region 4	Vd Arm	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,3367
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	14	11,97	103	88,03	NA	NA	NA	1,16	0,54	2,48	0,7062	0,5490
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,5490
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (by medical care situation)	Rest of the world	SVd Arm	78	10	12,82	68	87,18	NA	NA	NA	1,73	0,59	5,11	0,3116	0,5490
Patients with at least one AESI or AECI Hepatobiliary Disorders	Region (by medical care situation)	Rest of the world	Vd Arm	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,5490
Patients with at least one AESI or AECI Hepatobiliary Disorders	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	0,47	0,09	2,50	0,3643	0,1487
Patients with at least one AESI or AECI Hepatobiliary Disorders	Race	Races other than White	Vd Arm	42	6	14,29	36	85,71	NA	NA	NA	-	-	-	-	0,1487
Patients with at least one AESI or AECI Hepatobiliary Disorders	Race	White	SVd Arm	161	22	13,66	139	86,34	NA	NA	NA	1,79	0,88	3,65	0,1046	0,1487
Patients with at least one AESI or AECI Hepatobiliary Disorders	Race	White	Vd Arm	162	12	7,41	150	92,59	NA	NA	NA	-	-	-	-	0,1487

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Hepatobiliary Disorders	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	19	11,11	152	88,89	NA	NA	NA	1,16	0,60	2,24	0,6646	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	17	9,19	168	90,81	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Hepatobiliary Disorders	Prior PI therapies	N	SVd Arm	48	8	16,67	40	83,33	NA	NA	NA	2,79	0,73	10,60	0,1169	0,2117
Patients with at least one AESI or AECI Hepatobiliary Disorders	Prior PI therapies	N	Vd Arm	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,2117
Patients with at least one AESI or AECI Hepatobiliary Disorders	Prior PI therapies	Y	SVd Arm	147	16	10,88	131	89,12	NA	NA	NA	1,06	0,52	2,16	0,8634	0,2117
Patients with at least one AESI or AECI Hepatobiliary Disorders	Prior PI therapies	Y	Vd Arm	157	15	9,55	142	90,45	NA	NA	NA	-	-	-	-	0,2117
Patients with at least one AESI or AECI Hepatobiliary Disorders	Prior anti-MM regimen	>1	SVd Arm	98	13	13,27	85	86,73	NA	NA	NA	1,06	0,48	2,33	0,8874	0,3511
Patients with at least one AESI or AECI Hepatobiliary Disorders	Prior anti-MM regimen	>1	Vd Arm	104	12	11,54	92	88,46	NA	NA	NA	-	-	-	-	0,3511
Patients with at least one AESI or AECI Hepatobiliary Disorders	Prior anti-MM regimen	1	SVd Arm	97	11	11,34	86	88,66	NA	NA	NA	1,94	0,71	5,28	0,1865	0,3511
Patients with at least one AESI or AECI Hepatobiliary Disorders	Prior anti-MM regimen	1	Vd Arm	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,3511
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline single cytogenetic alterations	N	SVd Arm	98	11	11,22	87	88,78	NA	NA	NA	1,39	0,57	3,38	0,4604	0,7645
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline single cytogenetic alterations	N	Vd Arm	111	9	8,11	102	91,89	NA	NA	NA	-	-	-	-	0,7645
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline single cytogenetic alterations	Y	SVd Arm	97	13	13,40	84	86,60	NA	NA	NA	1,16	0,49	2,71	0,7405	0,7645
Patients with at least one AESI or AECI Hepatobiliary Disorders	Baseline single cytogenetic alterations	Y	Vd Arm	93	9	9,68	84	90,32	NA	NA	NA	-	-	-	-	0,7645
Patients with at least one AESI or AECI Hepatobiliary Disorders	Previously Exposed to Bortezomib	N	SVd Arm	61	11	18,03	50	81,97	NA	NA	NA	2,82	0,89	8,98	0,0669	0,1236
Patients with at least one AESI or AECI Hepatobiliary Disorders	Previously Exposed to Bortezomib	N	Vd Arm	62	4	6,45	58	93,55	NA	NA	NA	-	-	-	-	0,1236
Patients with at least one AESI or AECI Hepatobiliary Disorders	Previously Exposed to Bortezomib	Y	SVd Arm	134	13	9,70	121	90,30	NA	NA	NA	0,95	0,45	2,03	0,8981	0,1236
Patients with at least one AESI or AECI Hepatobiliary Disorders	Previously Exposed to Bortezomib	Y	Vd Arm	142	14	9,86	128	90,14	NA	NA	NA	-	-	-	-	0,1236
Patients with at least one AESI or AECI Cardiac Toxicity	total	-	SVd Arm	195	22	11,28	173	88,72	NA	NA	NA	3,09	1,30	7,33	0,0072	NA
Patients with at least one AESI or AECI Cardiac Toxicity	total	-	Vd Arm	204	7	3,43	197	96,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Gender	Female	SVd Arm	80	8	10,00	72	90,00	NA	NA	NA	2,31	0,68	7,85	0,1694	0,2622
Patients with at least one AESI or AECI Cardiac Toxicity	Gender	Female	Vd Arm	91	5	5,49	86	94,51	NA	NA	NA	-	-	-	-	0,2622
Patients with at least one AESI or AECI Cardiac Toxicity	Gender	Male	SVd Arm	115	14	12,17	101	87,83	NA	36,60	NA	6,96	1,56	31,03	0,0032	0,2622
Patients with at least one AESI or AECI Cardiac Toxicity	Gender	Male	Vd Arm	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,2622
Patients with at least one AESI or AECI Cardiac Toxicity	Age Group	<65	SVd Arm	86	11	12,79	75	87,21	NA	36,60	NA	4,04	0,87	18,75	0,0552	0,6121
Patients with at least one AESI or AECI Cardiac Toxicity	Age Group	<65	Vd Arm	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,6121
Patients with at least one AESI or AECI Cardiac Toxicity	Age Group	>=65	SVd Arm	109	11	10,09	98	89,91	NA	NA	NA	2,49	0,85	7,29	0,0871	0,6121

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Cardiac Toxicity	Age Group	>=65	Vd Arm	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,6121
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline R-ISS stage	Stage I or II	SVd Arm	173	16	9,25	157	90,75	NA	NA	NA	2,31	0,89	6,01	0,0766	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline R-ISS stage	Stage I or II	Vd Arm	174	6	3,45	168	96,55	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline ISS stage	Stage I or II	SVd Arm	163	14	8,59	149	91,41	NA	NA	NA	2,00	0,80	4,97	0,1291	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline ISS stage	Stage I or II	Vd Arm	173	7	4,05	166	95,95	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline ISS stage	Stage III	SVd Arm	32	8	25,00	24	75,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,8514
Patients with at least one AESI or AECI Cardiac Toxicity	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,8514
Patients with at least one AESI or AECI Cardiac Toxicity	Region (SAP)	Region 2	SVd Arm	61	6	9,84	55	90,16	NA	NA	NA	2,15	0,54	8,65	0,2690	0,8514
Patients with at least one AESI or AECI Cardiac Toxicity	Region (SAP)	Region 2	Vd Arm	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,8514
Patients with at least one AESI or AECI Cardiac Toxicity	Region (SAP)	Region 3	SVd Arm	47	5	10,64	42	89,36	NA	NA	NA	3,78	0,40	35,77	0,2161	0,8514
Patients with at least one AESI or AECI Cardiac Toxicity	Region (SAP)	Region 3	Vd Arm	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,8514
Patients with at least one AESI or AECI Cardiac Toxicity	Region (SAP)	Region 4	SVd Arm	69	8	11,59	61	88,41	NA	36,60	NA	3,70	0,76	17,98	0,0824	0,8514
Patients with at least one AESI or AECI Cardiac Toxicity	Region (SAP)	Region 4	Vd Arm	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,8514
Patients with at least one AESI or AECI Cardiac Toxicity	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	14	11,97	103	88,03	NA	NA	NA	3,89	1,24	12,19	0,0127	0,5245
Patients with at least one AESI or AECI Cardiac Toxicity	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	4	2,94	132	97,06	NA	NA	NA	-	-	-	-	0,5245
Patients with at least one AESI or AECI Cardiac Toxicity	Region (by medical care situation)	Rest of the world	SVd Arm	78	8	10,26	70	89,74	NA	36,60	NA	2,18	0,56	8,54	0,2517	0,5245
Patients with at least one AESI or AECI Cardiac Toxicity	Region (by medical care situation)	Rest of the world	Vd Arm	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,5245
Patients with at least one AESI or AECI Cardiac Toxicity	Race	Races other than White	SVd Arm	34	4	11,76	30	88,24	NA	NA	NA	2,64	0,44	15,90	0,2725	0,8346
Patients with at least one AESI or AECI Cardiac Toxicity	Race	Races other than White	Vd Arm	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,8346
Patients with at least one AESI or AECI Cardiac Toxicity	Race	White	SVd Arm	161	18	11,18	143	88,82	NA	NA	NA	3,28	1,20	9,00	0,0148	0,8346
Patients with at least one AESI or AECI Cardiac Toxicity	Race	White	Vd Arm	162	5	3,09	157	96,91	NA	NA	NA	-	-	-	-	0,8346
Patients with at least one AESI or AECI Cardiac Toxicity	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	18	10,53	153	89,47	NA	NA	NA	2,72	1,12	6,61	0,0221	NA
Patients with at least one AESI or AECI Cardiac Toxicity	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	7	3,78	178	96,22	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Cardiac Toxicity	Prior PI therapies	N	SVd Arm	48	5	10,42	43	89,58	NA	36,60	NA	1,49	0,27	8,33	0,6454	0,3593
Patients with at least one AESI or AECI Cardiac Toxicity	Prior PI therapies	N	Vd Arm	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,3593
Patients with at least one AESI or AECI Cardiac Toxicity	Prior PI therapies	Y	SVd Arm	147	17	11,56	130	88,44	NA	NA	NA	3,79	1,39	10,35	0,0054	0,3593
Patients with at least one AESI or AECI Cardiac Toxicity	Prior PI therapies	Y	Vd Arm	157	5	3,18	152	96,82	NA	NA	NA	-	-	-	-	0,3593
Patients with at least one AESI or AECI Cardiac Toxicity	Prior anti-MM regimen	>1	SVd Arm	98	8	8,16	90	91,84	NA	NA	NA	1,65	0,53	5,15	0,3821	0,1482
Patients with at least one AESI or AECI Cardiac Toxicity	Prior anti-MM regimen	>1	Vd Arm	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,1482
Patients with at least one AESI or AECI Cardiac Toxicity	Prior anti-MM regimen	1	SVd Arm	97	14	14,43	83	85,57	NA	36,60	NA	6,60	1,48	29,36	0,0044	0,1482
Patients with at least one AESI or AECI Cardiac Toxicity	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,1482
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline single cytogenetic alterations	N	SVd Arm	98	13	13,27	85	86,73	NA	36,60	NA	3,19	1,01	10,05	0,0373	0,9271
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline single cytogenetic alterations	N	Vd Arm	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,9271
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline single cytogenetic alterations	Y	SVd Arm	97	9	9,28	88	90,72	NA	NA	NA	2,94	0,77	11,19	0,0999	0,9271
Patients with at least one AESI or AECI Cardiac Toxicity	Baseline single cytogenetic alterations	Y	Vd Arm	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,9271
Patients with at least one AESI or AECI Cardiac Toxicity	Previously Exposed to Bortezomib	N	SVd Arm	61	7	11,48	54	88,52	NA	36,60	NA	1,37	0,32	5,85	0,6680	0,2130
Patients with at least one AESI or AECI Cardiac Toxicity	Previously Exposed to Bortezomib	N	Vd Arm	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,2130
Patients with at least one AESI or AECI Cardiac Toxicity	Previously Exposed to Bortezomib	Y	SVd Arm	134	15	11,19	119	88,81	NA	NA	NA	4,41	1,42	13,66	0,0052	0,2130
Patients with at least one AESI or AECI Cardiac Toxicity	Previously Exposed to Bortezomib	Y	Vd Arm	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,2130
Patients with at least one AESI or AECI Fatigue	total	-	SVd Arm	195	115	58,97	80	41,03	4,07	2,33	6,77	2,73	1,98	3,78	0,0000	NA
Patients with at least one AESI or AECI Fatigue	total	-	Vd Arm	204	57	27,94	147	72,06	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Fatigue	Gender	Female	SVd Arm	80	49	61,25	31	38,75	3,71	2,10	10,55	3,98	2,27	7,00	0,0000	0,0824
Patients with at least one AESI or AECI Fatigue	Gender	Female	Vd Arm	91	20	21,98	71	78,02	NA	NA	NA	-	-	-	-	0,0824
Patients with at least one AESI or AECI Fatigue	Gender	Male	SVd Arm	115	66	57,39	49	42,61	4,86	1,45	8,87	2,15	1,43	3,23	0,0002	0,0824
Patients with at least one AESI or AECI Fatigue	Gender	Male	Vd Arm	113	37	32,74	76	67,26	NA	12,88	NA	-	-	-	-	0,0824
Patients with at least one AESI or AECI Fatigue	Age Group	<65	SVd Arm	86	50	58,14	36	41,86	5,32	2,60	24,15	2,66	1,55	4,55	0,0002	0,7670
Patients with at least one AESI or AECI Fatigue	Age Group	<65	Vd Arm	75	21	28,00	54	72,00	NA	NA	NA	-	-	-	-	0,7670
Patients with at least one AESI or AECI Fatigue	Age Group	>=65	SVd Arm	109	65	59,63	44	40,37	3,68	1,28	8,87	2,95	1,94	4,47	0,0000	0,7670
Patients with at least one AESI or AECI Fatigue	Age Group	>=65	Vd Arm	129	36	27,91	93	72,09	NA	NA	NA	-	-	-	-	0,7670
Patients with at least one AESI or AECI Fatigue	Baseline R-ISS stage	Stage I or II	SVd Arm	173	102	58,96	71	41,04	4,57	2,46	8,05	2,73	1,93	3,86	0,0000	0,7057
Patients with at least one AESI or AECI Fatigue	Baseline R-ISS stage	Stage I or II	Vd Arm	174	48	27,59	126	72,41	NA	NA	NA	-	-	-	-	0,7057
Patients with at least one AESI or AECI Fatigue	Baseline R-ISS stage	Stage III	SVd Arm	12	6	50,00	6	50,00	1,41	0,69	NA	3,65	0,85	15,66	0,0683	0,7057
Patients with at least one AESI or AECI Fatigue	Baseline R-ISS stage	Stage III	Vd Arm	16	5	31,25	11	68,75	NA	8,61	NA	-	-	-	-	0,7057

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Fatigue	Baseline ISS stage	Stage I or II	SVd Arm	163	96	58,90	67	41,10	4,57	2,33	7,33	2,70	1,91	3,82	0,0000	0,8521
Patients with at least one AESI or AECI Fatigue	Baseline ISS stage	Stage I or II	Vd Arm	173	49	28,32	124	71,68	NA	NA	NA	-	-	-	-	0,8521
Patients with at least one AESI or AECI Fatigue	Baseline ISS stage	Stage III	SVd Arm	32	19	59,38	13	40,62	3,68	1,41	NA	2,95	1,27	6,83	0,0084	0,8521
Patients with at least one AESI or AECI Fatigue	Baseline ISS stage	Stage III	Vd Arm	31	8	25,81	23	74,19	NA	12,88	NA	-	-	-	-	0,8521
Patients with at least one AESI or AECI Fatigue	Region (SAP)	Region 1	SVd Arm	18	12	66,67	6	33,33	0,95	0,26	NA	4,35	1,19	15,87	0,0156	0,2293
Patients with at least one AESI or AECI Fatigue	Region (SAP)	Region 1	Vd Arm	17	5	29,41	12	70,59	NA	3,06	NA	-	-	-	-	0,2293
Patients with at least one AESI or AECI Fatigue	Region (SAP)	Region 2	SVd Arm	61	40	65,57	21	34,43	1,41	0,49	5,59	1,85	1,14	3,00	0,0120	0,2293
Patients with at least one AESI or AECI Fatigue	Region (SAP)	Region 2	Vd Arm	64	30	46,88	34	53,12	7,66	2,37	NA	-	-	-	-	0,2293
Patients with at least one AESI or AECI Fatigue	Region (SAP)	Region 3	SVd Arm	47	26	55,32	21	44,68	6,70	4,86	NA	3,66	1,65	8,13	0,0007	0,2293
Patients with at least one AESI or AECI Fatigue	Region (SAP)	Region 3	Vd Arm	53	8	15,09	45	84,91	NA	NA	NA	-	-	-	-	0,2293
Patients with at least one AESI or AECI Fatigue	Region (SAP)	Region 4	SVd Arm	69	37	53,62	32	46,38	5,59	3,68	NA	3,65	1,95	6,81	0,0000	0,2293
Patients with at least one AESI or AECI Fatigue	Region (SAP)	Region 4	Vd Arm	70	14	20,00	56	80,00	NA	NA	NA	-	-	-	-	0,2293
Patients with at least one AESI or AECI Fatigue	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	69	58,97	48	41,03	4,86	2,33	10,55	2,37	1,59	3,53	0,0000	0,3153
Patients with at least one AESI or AECI Fatigue	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	40	29,41	96	70,59	NA	NA	NA	-	-	-	-	0,3153
Patients with at least one AESI or AECI Fatigue	Region (by medical care situation)	Rest of the world	SVd Arm	78	46	58,97	32	41,03	4,07	1,45	24,15	3,39	1,91	6,00	0,0000	0,3153
Patients with at least one AESI or AECI Fatigue	Region (by medical care situation)	Rest of the world	Vd Arm	68	17	25,00	51	75,00	NA	NA	NA	-	-	-	-	0,3153
Patients with at least one AESI or AECI Fatigue	Race	Races other than White	SVd Arm	34	20	58,82	14	41,18	2,99	1,22	NA	2,08	1,03	4,20	0,0389	0,3986
Patients with at least one AESI or AECI Fatigue	Race	Races other than White	Vd Arm	42	16	38,10	26	61,90	NA	5,82	NA	-	-	-	-	0,3986
Patients with at least one AESI or AECI Fatigue	Race	White	SVd Arm	161	95	59,01	66	40,99	4,57	2,43	8,05	2,93	2,01	4,26	0,0000	0,3986
Patients with at least one AESI or AECI Fatigue	Race	White	Vd Arm	162	41	25,31	121	74,69	NA	NA	NA	-	-	-	-	0,3986
Patients with at least one AESI or AECI Fatigue	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	5	83,33	1	16,67	0,67	0,10	NA	3,93	0,42	36,69	0,1983	0,7500
Patients with at least one AESI or AECI Fatigue	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	3,75	2,37	NA	-	-	-	-	0,7500
Patients with at least one AESI or AECI Fatigue	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	99	57,89	72	42,11	4,86	2,46	8,05	2,72	1,93	3,85	0,0000	0,7500
Patients with at least one AESI or AECI Fatigue	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	50	27,03	135	72,97	NA	NA	NA	-	-	-	-	0,7500
Patients with at least one AESI or AECI Fatigue	Prior PI therapies	N	SVd Arm	48	24	50,00	24	50,00	8,87	1,68	NA	2,14	1,08	4,25	0,0265	0,4333
Patients with at least one AESI or AECI Fatigue	Prior PI therapies	N	Vd Arm	47	13	27,66	34	72,34	NA	NA	NA	-	-	-	-	0,4333
Patients with at least one AESI or AECI Fatigue	Prior PI therapies	Y	SVd Arm	147	91	61,90	56	38,10	3,68	1,87	6,70	2,92	2,03	4,21	0,0000	0,4333
Patients with at least one AESI or AECI Fatigue	Prior PI therapies	Y	Vd Arm	157	44	28,03	113	71,97	NA	NA	NA	-	-	-	-	0,4333
Patients with at least one AESI or AECI Fatigue	Prior anti-MM regimen	>1	SVd Arm	98	56	57,14	42	42,86	5,59	2,33	10,84	2,30	1,48	3,59	0,0001	0,2819

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Fatigue	Prior anti-MM regimen	>1	Vd Arm	104	31	29,81	73	70,19	NA	12,88	NA	-	-	-	-	0,2819
Patients with at least one AESI or AECI Fatigue	Prior anti-MM regimen	1	SVd Arm	97	59	60,82	38	39,18	3,58	1,41	8,87	3,29	2,05	5,27	0,0000	0,2819
Patients with at least one AESI or AECI Fatigue	Prior anti-MM regimen	1	Vd Arm	100	26	26,00	74	74,00	NA	NA	NA	-	-	-	-	0,2819
Patients with at least one AESI or AECI Fatigue	Baseline single cytogenetic alterations	N	SVd Arm	98	54	55,10	44	44,90	5,59	2,43	24,15	2,44	1,55	3,83	0,0001	0,6976
Patients with at least one AESI or AECI Fatigue	Baseline single cytogenetic alterations	N	Vd Arm	111	32	28,83	79	71,17	NA	NA	NA	-	-	-	-	0,6976
Patients with at least one AESI or AECI Fatigue	Baseline single cytogenetic alterations	Y	SVd Arm	97	61	62,89	36	37,11	3,48	1,41	6,77	2,77	1,73	4,44	0,0000	0,6976
Patients with at least one AESI or AECI Fatigue	Baseline single cytogenetic alterations	Y	Vd Arm	93	25	26,88	68	73,12	NA	NA	NA	-	-	-	-	0,6976
Patients with at least one AESI or AECI Fatigue	Previously Exposed to Bortezomib	N	SVd Arm	61	33	54,10	28	45,90	5,82	1,68	NA	2,70	1,44	5,05	0,0013	0,8983
Patients with at least one AESI or AECI Fatigue	Previously Exposed to Bortezomib	N	Vd Arm	62	15	24,19	47	75,81	NA	NA	NA	-	-	-	-	0,8983
Patients with at least one AESI or AECI Fatigue	Previously Exposed to Bortezomib	Y	SVd Arm	134	82	61,19	52	38,81	3,58	1,87	6,70	2,83	1,94	4,14	0,0000	0,8983
Patients with at least one AESI or AECI Fatigue	Previously Exposed to Bortezomib	Y	Vd Arm	142	42	29,58	100	70,42	NA	NA	NA	-	-	-	-	0,8983
Patients with at least one AESI or AECI Haemorrhages	total	-	SVd Arm	195	35	17,95	160	82,05	NA	32,43	NA	2,64	1,43	4,88	0,0013	NA
Patients with at least one AESI or AECI Haemorrhages	total	-	Vd Arm	204	15	7,35	189	92,65	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Haemorrhages	Gender	Female	SVd Arm	80	12	15,00	68	85,00	NA	NA	NA	1,59	0,61	4,11	0,3401	0,2424
Patients with at least one AESI or AECI Haemorrhages	Gender	Female	Vd Arm	91	9	9,89	82	90,11	NA	NA	NA	-	-	-	-	0,2424
Patients with at least one AESI or AECI Haemorrhages	Gender	Male	SVd Arm	115	23	20,00	92	80,00	NA	32,43	NA	3,47	1,41	8,56	0,0041	0,2424
Patients with at least one AESI or AECI Haemorrhages	Gender	Male	Vd Arm	113	6	5,31	107	94,69	NA	NA	NA	-	-	-	-	0,2424
Patients with at least one AESI or AECI Haemorrhages	Age Group	<65	SVd Arm	86	17	19,77	69	80,23	NA	32,43	NA	4,02	1,31	12,31	0,0092	0,4115
Patients with at least one AESI or AECI Haemorrhages	Age Group	<65	Vd Arm	75	4	5,33	71	94,67	NA	NA	NA	-	-	-	-	0,4115
Patients with at least one AESI or AECI Haemorrhages	Age Group	>=65	SVd Arm	109	18	16,51	91	83,49	NA	29,31	NA	2,27	1,04	4,95	0,0350	0,4115
Patients with at least one AESI or AECI Haemorrhages	Age Group	>=65	Vd Arm	129	11	8,53	118	91,47	NA	NA	NA	-	-	-	-	0,4115
Patients with at least one AESI or AECI Haemorrhages	Baseline R-ISS stage	Stage I or II	SVd Arm	173	31	17,92	142	82,08	NA	NA	NA	2,54	1,30	4,97	0,0046	0,6035
Patients with at least one AESI or AECI Haemorrhages	Baseline R-ISS stage	Stage I or II	Vd Arm	174	12	6,90	162	93,10	NA	NA	NA	-	-	-	-	0,6035
Patients with at least one AESI or AECI Haemorrhages	Baseline R-ISS stage	Stage III	SVd Arm	12	3	25,00	9	75,00	32,43	NA	NA	1,47	0,21	10,33	0,6950	0,6035
Patients with at least one AESI or AECI Haemorrhages	Baseline R-ISS stage	Stage III	Vd Arm	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,6035
Patients with at least one AESI or AECI Haemorrhages	Baseline ISS stage	Stage I or II	SVd Arm	163	30	18,40	133	81,60	NA	NA	NA	2,61	1,33	5,10	0,0036	0,5030
Patients with at least one AESI or AECI Haemorrhages	Baseline ISS stage	Stage I or II	Vd Arm	173	12	6,94	161	93,06	NA	NA	NA	-	-	-	-	0,5030
Patients with at least one AESI or AECI Haemorrhages	Baseline ISS stage	Stage III	SVd Arm	32	5	15,62	27	84,38	32,43	32,43	NA	1,48	0,32	6,75	0,6101	0,5030
Patients with at least one AESI or AECI Haemorrhages	Baseline ISS stage	Stage III	Vd Arm	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,5030
Patients with at least one AESI or AECI Haemorrhages	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	NA	16,76	NA	1,86	0,19	18,53	0,5904	0,2534

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Haemorrhages	Region (SAP)	Region 1	Vd Arm	17	3	17,65	14	82,35	NA	NA	NA	-	-	-	-	0,2534
Patients with at least one AESI or AECI Haemorrhages	Region (SAP)	Region 2	SVd Arm	61	13	21,31	48	78,69	29,31	21,91	NA	1,50	0,61	3,68	0,3765	0,2534
Patients with at least one AESI or AECI Haemorrhages	Region (SAP)	Region 2	Vd Arm	64	8	12,50	56	87,50	NA	NA	NA	-	-	-	-	0,2534
Patients with at least one AESI or AECI Haemorrhages	Region (SAP)	Region 3	SVd Arm	47	5	10,64	42	89,36	NA	NA	NA	2,24	0,42	12,09	0,3356	0,2534
Patients with at least one AESI or AECI Haemorrhages	Region (SAP)	Region 3	Vd Arm	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,2534
Patients with at least one AESI or AECI Haemorrhages	Region (SAP)	Region 4	SVd Arm	69	14	20,29	55	79,71	NA	32,43	NA	8,97	2,00	40,16	0,0006	0,2534
Patients with at least one AESI or AECI Haemorrhages	Region (SAP)	Region 4	Vd Arm	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,2534
Patients with at least one AESI or AECI Haemorrhages	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	16	13,68	101	86,32	NA	29,31	NA	1,34	0,64	2,83	0,4339	0,0157
Patients with at least one AESI or AECI Haemorrhages	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,0157
Patients with at least one AESI or AECI Haemorrhages	Region (by medical care situation)	Rest of the world	SVd Arm	78	19	24,36	59	75,64	NA	32,43	NA	10,24	2,35	44,51	0,0001	0,0157
Patients with at least one AESI or AECI Haemorrhages	Region (by medical care situation)	Rest of the world	Vd Arm	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,0157
Patients with at least one AESI or AECI Haemorrhages	Race	Races other than White	SVd Arm	34	6	17,65	28	82,35	32,43	32,43	NA	2,80	0,53	14,73	0,2061	0,8094
Patients with at least one AESI or AECI Haemorrhages	Race	Races other than White	Vd Arm	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,8094
Patients with at least one AESI or AECI Haemorrhages	Race	White	SVd Arm	161	29	18,01	132	81,99	NA	NA	NA	2,25	1,15	4,37	0,0148	0,8094
Patients with at least one AESI or AECI Haemorrhages	Race	White	Vd Arm	162	13	8,02	149	91,98	NA	NA	NA	-	-	-	-	0,8094
Patients with at least one AESI or AECI Haemorrhages	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Haemorrhages	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AESI or AECI Haemorrhages	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	32	18,71	139	81,29	NA	32,43	NA	3,17	1,62	6,21	0,0004	NA
Patients with at least one AESI or AECI Haemorrhages	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	13	7,03	172	92,97	NA	NA	NA	-	-	-	-	NA
Patients with at least one AESI or AECI Haemorrhages	Prior PI therapies	N	SVd Arm	48	10	20,83	38	79,17	NA	NA	NA	5,88	1,24	27,88	0,0128	0,2497
Patients with at least one AESI or AECI Haemorrhages	Prior PI therapies	N	Vd Arm	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,2497
Patients with at least one AESI or AECI Haemorrhages	Prior PI therapies	Y	SVd Arm	147	25	17,01	122	82,99	32,43	29,31	NA	2,17	1,10	4,27	0,0214	0,2497
Patients with at least one AESI or AECI Haemorrhages	Prior PI therapies	Y	Vd Arm	157	13	8,28	144	91,72	NA	NA	NA	-	-	-	-	0,2497
Patients with at least one AESI or AECI Haemorrhages	Prior anti-MM regimen	>1	SVd Arm	98	14	14,29	84	85,71	NA	NA	NA	2,39	0,96	5,98	0,0552	0,7761
Patients with at least one AESI or AECI Haemorrhages	Prior anti-MM regimen	>1	Vd Arm	104	7	6,73	97	93,27	NA	NA	NA	-	-	-	-	0,7761
Patients with at least one AESI or AECI Haemorrhages	Prior anti-MM regimen	1	SVd Arm	97	21	21,65	76	78,35	NA	29,31	NA	2,86	1,25	6,54	0,0095	0,7761
Patients with at least one AESI or AECI Haemorrhages	Prior anti-MM regimen	1	Vd Arm	100	8	8,00	92	92,00	NA	NA	NA	-	-	-	-	0,7761
Patients with at least one AESI or AECI Haemorrhages	Baseline single cytogenetic alterations	N	SVd Arm	98	21	21,43	77	78,57	NA	32,43	NA	3,33	1,45	7,64	0,0028	0,3064
Patients with at least one AESI or AECI Haemorrhages	Baseline single cytogenetic alterations	N	Vd Arm	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,3064

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Haemorrhages	Baseline single cytogenetic alterations	Y	SVd Arm	97	14	14,43	83	85,57	NA	29,31	NA	1,75	0,70	4,35	0,2265	0,3064
Patients with at least one AESI or AECI Haemorrhages	Baseline single cytogenetic alterations	Y	Vd Arm	93	7	7,53	86	92,47	NA	NA	NA	-	-	-	-	0,3064
Patients with at least one AESI or AECI Haemorrhages	Previously Exposed to Bortezomib	N	SVd Arm	61	12	19,67	49	80,33	NA	NA	NA	6,74	1,44	31,42	0,0058	0,1728
Patients with at least one AESI or AECI Haemorrhages	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,1728
Patients with at least one AESI or AECI Haemorrhages	Previously Exposed to Bortezomib	Y	SVd Arm	134	23	17,16	111	82,84	NA	29,31	NA	2,08	1,04	4,17	0,0351	0,1728
Patients with at least one AESI or AECI Haemorrhages	Previously Exposed to Bortezomib	Y	Vd Arm	142	13	9,15	129	90,85	NA	NA	NA	-	-	-	-	0,1728
Patients with at least one AESI or AECI Neuropathy Peripheral	total	-	SVd Arm	195	66	33,85	129	66,15	25,33	13,83	NA	0,60	0,44	0,82	0,0013	NA
Patients with at least one AESI or AECI Neuropathy Peripheral	total	-	Vd Arm	204	99	48,53	105	51,47	7,20	4,86	19,12	-	-	-	-	NA
Patients with at least one AESI or AECI Neuropathy Peripheral	Gender	Female	SVd Arm	80	29	36,25	51	63,75	25,33	7,98	NA	0,59	0,36	0,96	0,0328	0,9756
Patients with at least one AESI or AECI Neuropathy Peripheral	Gender	Female	Vd Arm	91	44	48,35	47	51,65	7,00	4,86	NA	-	-	-	-	0,9756
Patients with at least one AESI or AECI Neuropathy Peripheral	Gender	Male	SVd Arm	115	37	32,17	78	67,83	25,79	14,55	NA	0,58	0,38	0,89	0,0120	0,9756
Patients with at least one AESI or AECI Neuropathy Peripheral	Gender	Male	Vd Arm	113	55	48,67	58	51,33	13,11	3,81	21,75	-	-	-	-	0,9756
Patients with at least one AESI or AECI Neuropathy Peripheral	Age Group	<65	SVd Arm	86	30	34,88	56	65,12	25,33	8,54	NA	0,54	0,33	0,89	0,0153	0,6628
Patients with at least one AESI or AECI Neuropathy Peripheral	Age Group	<65	Vd Arm	75	37	49,33	38	50,67	7,20	4,17	NA	-	-	-	-	0,6628
Patients with at least one AESI or AECI Neuropathy Peripheral	Age Group	>=65	SVd Arm	109	36	33,03	73	66,97	37,98	8,08	NA	0,63	0,41	0,96	0,0286	0,6628
Patients with at least one AESI or AECI Neuropathy Peripheral	Age Group	>=65	Vd Arm	129	62	48,06	67	51,94	7,56	4,14	21,75	-	-	-	-	0,6628
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline R-ISS stage	Stage I or II	SVd Arm	173	61	35,26	112	64,74	25,33	9,95	NA	0,61	0,44	0,85	0,0030	0,7890
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline R-ISS stage	Stage I or II	Vd Arm	174	86	49,43	88	50,57	6,77	4,86	19,15	-	-	-	-	0,7890
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline R-ISS stage	Stage III	SVd Arm	12	3	25,00	9	75,00	25,79	7,10	NA	0,47	0,07	2,98	0,4171	0,7890
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline R-ISS stage	Stage III	Vd Arm	16	4	25,00	12	75,00	NA	7,56	NA	-	-	-	-	0,7890
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline ISS stage	Stage I or II	SVd Arm	163	59	36,20	104	63,80	25,33	8,54	NA	0,60	0,43	0,84	0,0029	0,8986
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline ISS stage	Stage I or II	Vd Arm	173	86	49,71	87	50,29	7,00	4,86	19,15	-	-	-	-	0,8986
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline ISS stage	Stage III	SVd Arm	32	7	21,88	25	78,12	NA	25,79	NA	0,57	0,22	1,44	0,2267	0,8986
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline ISS stage	Stage III	Vd Arm	31	13	41,94	18	58,06	13,11	4,37	NA	-	-	-	-	0,8986
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (SAP)	Region 1	SVd Arm	18	2	11,11	16	88,89	NA	9,95	NA	0,22	0,04	1,09	0,0435	0,3791
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (SAP)	Region 1	Vd Arm	17	8	47,06	9	52,94	6,77	1,41	NA	-	-	-	-	0,3791
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (SAP)	Region 2	SVd Arm	61	22	36,07	39	63,93	14,55	6,87	NA	0,62	0,35	1,07	0,0820	0,3791
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (SAP)	Region 2	Vd Arm	64	33	51,56	31	48,44	4,14	2,76	NA	-	-	-	-	0,3791
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (SAP)	Region 3	SVd Arm	47	22	46,81	25	53,19	18,53	6,34	NA	0,89	0,48	1,63	0,6952	0,3791
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (SAP)	Region 3	Vd Arm	53	25	47,17	28	52,83	7,20	3,58	NA	-	-	-	-	0,3791

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (SAP)	Region 4	SVd Arm	69	20	28,99	49	71,01	25,79	25,33	NA	0,55	0,31	0,97	0,0380	0,3791
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (SAP)	Region 4	Vd Arm	70	33	47,14	37	52,86	14,52	5,78	NA	-	-	-	-	0,3791
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	42	35,90	75	64,10	18,53	8,54	NA	0,64	0,43	0,95	0,0271	0,5891
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	63	46,32	73	53,68	7,00	4,14	NA	-	-	-	-	0,5891
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (by medical care situation)	Rest of the world	SVd Arm	78	24	30,77	54	69,23	25,79	13,83	NA	0,53	0,31	0,90	0,0174	0,5891
Patients with at least one AESI or AECI Neuropathy Peripheral	Region (by medical care situation)	Rest of the world	Vd Arm	68	36	52,94	32	47,06	14,36	4,37	NA	-	-	-	-	0,5891
Patients with at least one AESI or AECI Neuropathy Peripheral	Race	Races other than White	SVd Arm	34	11	32,35	23	67,65	25,79	7,10	NA	0,38	0,16	0,87	0,0180	0,2528
Patients with at least one AESI or AECI Neuropathy Peripheral	Race	Races other than White	Vd Arm	42	26	61,90	16	38,10	4,37	2,89	21,75	-	-	-	-	0,2528
Patients with at least one AESI or AECI Neuropathy Peripheral	Race	White	SVd Arm	161	55	34,16	106	65,84	25,33	9,95	NA	0,64	0,45	0,91	0,0137	0,2528
Patients with at least one AESI or AECI Neuropathy Peripheral	Race	White	Vd Arm	162	73	45,06	89	54,94	8,97	4,86	NA	-	-	-	-	0,2528
Patients with at least one AESI or AECI Neuropathy Peripheral	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	7,98	5,55	NA	0,64	0,09	4,62	0,6540	0,9545
Patients with at least one AESI or AECI Neuropathy Peripheral	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	NA	4,14	NA	-	-	-	-	0,9545
Patients with at least one AESI or AECI Neuropathy Peripheral	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	56	32,75	115	67,25	25,79	13,83	NA	0,60	0,43	0,85	0,0031	0,9545
Patients with at least one AESI or AECI Neuropathy Peripheral	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	89	48,11	96	51,89	7,20	4,86	19,12	-	-	-	-	0,9545
Patients with at least one AESI or AECI Neuropathy Peripheral	Prior PI therapies	N	SVd Arm	48	15	31,25	33	68,75	37,98	8,54	NA	0,39	0,20	0,75	0,0035	0,1346
Patients with at least one AESI or AECI Neuropathy Peripheral	Prior PI therapies	N	Vd Arm	47	26	55,32	21	44,68	4,86	2,79	NA	-	-	-	-	0,1346
Patients with at least one AESI or AECI Neuropathy Peripheral	Prior PI therapies	Y	SVd Arm	147	51	34,69	96	65,31	18,53	9,95	NA	0,69	0,48	0,98	0,0395	0,1346
Patients with at least one AESI or AECI Neuropathy Peripheral	Prior PI therapies	Y	Vd Arm	157	73	46,50	84	53,50	8,97	5,78	21,75	-	-	-	-	0,1346
Patients with at least one AESI or AECI Neuropathy Peripheral	Prior anti-MM regimen	>1	SVd Arm	98	28	28,57	70	71,43	37,98	13,83	NA	0,53	0,33	0,87	0,0100	0,5475
Patients with at least one AESI or AECI Neuropathy Peripheral	Prior anti-MM regimen	>1	Vd Arm	104	45	43,27	59	56,73	13,11	4,86	NA	-	-	-	-	0,5475
Patients with at least one AESI or AECI Neuropathy Peripheral	Prior anti-MM regimen	1	SVd Arm	97	38	39,18	59	60,82	18,53	8,54	NA	0,65	0,43	0,99	0,0432	0,5475
Patients with at least one AESI or AECI Neuropathy Peripheral	Prior anti-MM regimen	1	Vd Arm	100	54	54,00	46	46,00	6,44	3,32	19,15	-	-	-	-	0,5475
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline single cytogenetic alterations	N	SVd Arm	98	29	29,59	69	70,41	37,98	25,33	NA	0,45	0,28	0,72	0,0006	0,0744
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline single cytogenetic alterations	N	Vd Arm	111	58	52,25	53	47,75	6,44	3,81	20,96	-	-	-	-	0,0744
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline single cytogenetic alterations	Y	SVd Arm	97	37	38,14	60	61,86	13,83	7,10	NA	0,82	0,52	1,29	0,3839	0,0744
Patients with at least one AESI or AECI Neuropathy Peripheral	Baseline single cytogenetic alterations	Y	Vd Arm	93	41	44,09	52	55,91	14,36	5,78	NA	-	-	-	-	0,0744
Patients with at least one AESI or AECI Neuropathy Peripheral	Previously Exposed to Bortezomib	N	SVd Arm	61	23	37,70	38	62,30	37,98	7,43	NA	0,49	0,28	0,88	0,0152	0,5381
Patients with at least one AESI or AECI Neuropathy Peripheral	Previously Exposed to Bortezomib	N	Vd Arm	62	33	53,23	29	46,77	4,17	2,79	NA	-	-	-	-	0,5381
Patients with at least one AESI or AECI Neuropathy Peripheral	Previously Exposed to Bortezomib	Y	SVd Arm	134	43	32,09	91	67,91	25,33	13,83	NA	0,61	0,42	0,90	0,0128	0,5381

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AESI or AECI Neuropathy Peripheral	Previously Exposed to Bortezomib	Y	Vd Arm	142	66	46,48	76	53,52	8,97	6,01	21,75	-	-	-	-	0,5381
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	total	-	SVd Arm	195	108	55,38	~~87~~	~~44,62~~	~~4,37~~	~~2,30~~	~~10,64~~	~~3,77~~	~~2,60~~	~~5,46~~	~~0,0000~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	total	-	Vd Arm	204	39	19,12	~~165~~	~~80,88~~	~~NA~~	~~NA~~	~~NA~~	~~-~~	~~-~~	~~-~~	~~-~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Gender	Female	SVd Arm	80	39	48,75	41	51,25	19,45	3,71	NA	3,26	1,79	5,94	0,0001	0,3574
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Gender	Female	Vd Arm	91	18	19,78	73	80,22	NA	NA	NA	-	-	-	-	0,3574
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Gender	Male	SVd Arm	115	69	60,00	46	40,00	2,79	1,64	8,34	4,70	2,86	7,74	0,0000	0,3574
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Gender	Male	Vd Arm	113	21	18,58	92	81,42	NA	NA	NA	-	-	-	-	0,3574
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Age Group	<65	SVd Arm	86	47	54,65	39	45,35	7,13	3,45	23,26	3,11	1,74	5,55	0,0001	0,3341
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Age Group	<65	Vd Arm	75	16	21,33	59	78,67	NA	NA	NA	-	-	-	-	0,3341
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Age Group	>=65	SVd Arm	109	61	55,96	48	44,04	2,73	1,41	21,06	4,52	2,77	7,39	0,0000	0,3341
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Age Group	>=65	Vd Arm	129	23	17,83	106	82,17	NA	NA	NA	-	-	-	-	0,3341
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	95	54,91	78	45,09	4,86	2,73	19,45	3,82	2,55	5,71	0,0000	0,7287
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	32	18,39	142	81,61	NA	NA	NA	-	-	-	-	0,7287
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline R-ISS stage	Stage III	SVd Arm	12	9	75,00	3	25,00	1,41	1,41	NA	3,04	0,88	10,43	0,0673	0,7287
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline R-ISS stage	Stage III	Vd Arm	16	4	25,00	12	75,00	NA	NA	NA	-	-	-	-	0,7287
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline ISS stage	Stage I or II	SVd Arm	163	89	54,60	74	45,40	4,86	2,30	19,45	3,79	2,53	5,70	0,0000	0,6001
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline ISS stage	Stage I or II	Vd Arm	173	32	18,50	141	81,50	NA	NA	NA	-	-	-	-	0,6001
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline ISS stage	Stage III	SVd Arm	32	19	59,38	13	40,62	2,73	1,41	NA	2,93	1,22	7,04	0,0120	0,6001

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline ISS stage	Stage III	Vd Arm	31	7	22,58	24	77,42	NA	NA	NA	-	-	-	-	0,6001
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (SAP)	Region 1	SVd Arm	18	11	61,11	7	38,89	4,86	0,72	NA	2,96	0,76	11,56	0,1039	0,6592
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (SAP)	Region 1	Vd Arm	17	4	23,53	13	76,47	NA	NA	NA	-	-	-	-	0,6592
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (SAP)	Region 2	SVd Arm	61	39	63,93	22	36,07	1,64	1,41	7,13	2,92	1,66	5,13	0,0001	0,6592
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (SAP)	Region 2	Vd Arm	64	19	29,69	45	70,31	NA	20,47	NA	-	-	-	-	0,6592
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (SAP)	Region 3	SVd Arm	47	22	46,81	25	53,19	15,24	4,37	NA	4,79	1,91	12,01	0,0003	0,6592
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (SAP)	Region 3	Vd Arm	53	6	11,32	47	88,68	NA	NA	NA	-	-	-	-	0,6592
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (SAP)	Region 4	SVd Arm	69	36	52,17	33	47,83	7,59	2,79	NA	4,80	2,36	9,73	0,0000	0,6592
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (SAP)	Region 4	Vd Arm	70	10	14,29	60	85,71	NA	NA	NA	-	-	-	-	0,6592
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	62	52,99	55	47,01	6,93	2,10	NA	2,88	1,86	4,48	0,0000	0,0680
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	30	22,06	106	77,94	NA	NA	NA	-	-	-	-	0,0680
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (by medical care situation)	Rest of the world	SVd Arm	78	46	58,97	32	41,03	3,78	1,81	21,06	6,34	3,08	13,06	0,0000	0,0680
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Region (by medical care situation)	Rest of the world	Vd Arm	68	9	13,24	59	86,76	NA	NA	NA	-	-	-	-	0,0680
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Race	Races other than White	SVd Arm	34	17	50,00	17	50,00	7,13	2,10	NA	7,03	2,24	22,08	0,0002	0,2388
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Race	Races other than White	Vd Arm	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,2388
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Race	White	SVd Arm	161	91	56,52	70	43,48	4,17	1,87	10,64	3,39	2,28	5,05	0,0000	0,2388
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Race	White	Vd Arm	162	34	20,99	128	79,01	NA	NA	NA	-	-	-	-	0,2388
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	4	66,67	2	33,33	1,41	0,26	NA	1,96	0,20	19,15	0,5577	0,5363

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	NA	1,05	NA	-	-	-	-	0,5363
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	95	55,56	76	44,44	4,37	2,73	15,24	4,06	2,72	6,07	0,0000	0,5363
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	34	18,38	151	81,62	NA	NA	NA	-	-	-	-	0,5363
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Prior PI therapies	N	SVd Arm	48	25	52,08	23	47,92	6,93	2,30	NA	3,94	1,76	8,84	0,0003	0,9014
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Prior PI therapies	N	Vd Arm	47	8	17,02	39	82,98	NA	NA	NA	-	-	-	-	0,9014
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Prior PI therapies	Y	SVd Arm	147	83	56,46	64	43,54	4,17	1,87	9,99	3,72	2,46	5,65	0,0000	0,9014
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Prior PI therapies	Y	Vd Arm	157	31	19,75	126	80,25	NA	NA	NA	-	-	-	-	0,9014
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Prior anti-MM regimen	>1	SVd Arm	98	54	55,10	44	44,90	4,17	1,81	NA	4,31	2,49	7,46	0,0000	0,5047
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Prior anti-MM regimen	>1	Vd Arm	104	17	16,35	87	83,65	NA	NA	NA	-	-	-	-	0,5047
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Prior anti-MM regimen	1	SVd Arm	97	54	55,67	43	44,33	6,93	2,10	20,73	3,35	2,03	5,53	0,0000	0,5047
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Prior anti-MM regimen	1	Vd Arm	100	22	22,00	78	78,00	NA	NA	NA	-	-	-	-	0,5047
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline single cytogenetic alterations	N	SVd Arm	98	51	52,04	47	47,96	7,43	2,10	19,45	3,57	2,13	5,98	0,0000	0,8740
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline single cytogenetic alterations	N	Vd Arm	111	21	18,92	90	81,08	NA	NA	NA	-	-	-	-	0,8740
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline single cytogenetic alterations	Y	SVd Arm	97	57	58,76	40	41,24	3,78	1,68	21,06	3,79	2,20	6,54	0,0000	0,8740
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Baseline single cytogenetic alterations	Y	Vd Arm	93	18	19,35	75	80,65	NA	NA	NA	-	-	-	-	0,8740
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Previously Exposed to Bortezomib	N	SVd Arm	61	30	49,18	31	50,82	10,64	2,30	NA	3,17	1,60	6,26	0,0005	0,5327
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Previously Exposed to Bortezomib	N	Vd Arm	62	12	19,35	50	80,65	NA	NA	NA	-	-	-	-	0,5327
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Previously Exposed to Bortezomib	Y	SVd Arm	134	78	58,21	56	41,79	3,78	1,68	8,34	4,10	2,64	6,39	0,0000	0,5327

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Thrombocytopenia	Previously Exposed to Bortezomib	Y	Vd Arm	142	27	19,01	115	80,99	NA	NA	NA	-	-	-	-	0,5327
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	total	-	SVd Arm	195	23	11,79	~~172~~	~~88,21~~	~~NA~~	~~NA~~	~~NA~~	~~3,54~~	~~1,52~~	~~8,27~~	~~0,0018~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	total	-	Vd Arm	204	7	3,43	~~197~~	~~96,57~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Gender	Female	SVd Arm	80	12	15,00	68	85,00	NA	NA	NA	3,60	1,12	11,58	0,0229	0,9784
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Gender	Female	Vd Arm	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,9784
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Gender	Male	SVd Arm	115	11	9,57	104	90,43	NA	NA	NA	3,69	1,02	13,30	0,0325	0,9784
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Gender	Male	Vd Arm	113	3	2,65	110	97,35	NA	NA	NA	-	-	-	-	0,9784
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Age Group	<65	SVd Arm	86	13	15,12	73	84,88	NA	NA	NA	12,98	1,68	100,09	0,0016	0,1058
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Age Group	<65	Vd Arm	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,1058
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Age Group	>=65	SVd Arm	109	10	9,17	99	90,83	NA	NA	NA	1,97	0,71	5,48	0,1847	0,1058
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Age Group	>=65	Vd Arm	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	0,1058
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	22	12,72	151	87,28	NA	NA	NA	3,70	1,50	9,14	0,0024	0,4085
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	6	3,45	168	96,55	NA	NA	NA	-	-	-	-	0,4085
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	NA	NA	NA	0,98	0,05	19,99	0,9906	0,4085
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,4085
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline ISS stage	Stage I or II	SVd Arm	163	21	12,88	142	87,12	NA	NA	NA	3,72	1,50	9,22	0,0023	0,6327
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline ISS stage	Stage I or II	Vd Arm	173	6	3,47	167	96,53	NA	NA	NA	-	-	-	-	0,6327
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	NA	NA	NA	1,99	0,18	22,03	0,5683	0,6327

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,6327
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	NA	NA	NA	NA	NA	NA	1,0000	0,2182
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	0,2182
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (SAP)	Region 2	SVd Arm	61	7	11,48	54	88,52	NA	19,58	NA	4,27	0,85	21,58	0,0592	0,2182
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (SAP)	Region 2	Vd Arm	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,2182
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (SAP)	Region 3	SVd Arm	47	5	10,64	42	89,36	NA	NA	NA	1,14	0,30	4,34	0,8430	0,2182
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (SAP)	Region 3	Vd Arm	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,2182
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (SAP)	Region 4	SVd Arm	69	10	14,49	59	85,51	-	-	-	-	-	-	-	0,2182
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	0,2182
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	14	11,97	103	88,03	NA	NA	NA	2,33	0,93	5,83	0,0620	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	7	5,15	129	94,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (by medical care situation)	Rest of the world	SVd Arm	78	9	11,54	69	88,46	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Race	White	SVd Arm	161	21	13,04	140	86,96	NA	NA	NA	2,91	1,23	6,89	0,0108	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Race	White	Vd Arm	162	7	4,32	155	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	20	11,70	151	88,30	NA	NA	NA	3,12	1,31	7,40	0,0067	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	7	3,78	178	96,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Prior PI therapies	N	SVd Arm	48	3	6,25	45	93,75	NA	NA	NA	1,33	0,22	8,00	0,7531	0,2454
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Prior PI therapies	N	Vd Arm	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,2454
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Prior PI therapies	Y	SVd Arm	147	20	13,61	127	86,39	NA	NA	NA	4,47	1,68	11,94	0,0011	0,2454
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Prior PI therapies	Y	Vd Arm	157	5	3,18	152	96,82	NA	NA	NA	-	-	-	-	0,2454
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Prior anti-MM regimen	>1	SVd Arm	98	13	13,27	85	86,73	NA	NA	NA	2,68	0,95	7,53	0,0516	0,4147
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Prior anti-MM regimen	>1	Vd Arm	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,4147
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Prior anti-MM regimen	1	SVd Arm	97	10	10,31	87	89,69	NA	NA	NA	5,76	1,26	26,44	0,0109	0,4147
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,4147
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline single cytogenetic alterations	N	SVd Arm	98	7	7,14	91	92,86	NA	NA	NA	2,29	0,66	7,89	0,1783	0,3414
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline single cytogenetic alterations	N	Vd Arm	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,3414
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline single cytogenetic alterations	Y	SVd Arm	97	16	16,49	81	83,51	NA	NA	NA	5,36	1,55	18,53	0,0031	0,3414
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Baseline single cytogenetic alterations	Y	Vd Arm	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,3414
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Previously Exposed to Bortezomib	N	SVd Arm	61	5	8,20	56	91,80	NA	NA	NA	2,01	0,46	8,80	0,3458	0,3095
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Previously Exposed to Bortezomib	N	Vd Arm	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,3095
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Previously Exposed to Bortezomib	Y	SVd Arm	134	18	13,43	116	86,57	NA	NA	NA	5,20	1,75	15,41	0,0009	0,3095

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neutropenia	Previously Exposed to Bortezomib	Y	Vd Arm	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,3095
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	total	-	SVd Arm	195	96	49,23	~~99~~	~~50,77~~	~~6,01~~	~~2,79~~	~~NA~~	~~6,43~~	~~4,00~~	~~10,33~~	~~0,0000~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	total	-	Vd Arm	204	21	10,29	~~183~~	~~89,71~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Gender	Female	SVd Arm	80	46	57,50	34	42,50	2,99	1,64	NA	7,38	3,58	15,22	0,0000	0,7919
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Gender	Female	Vd Arm	91	11	12,09	80	87,91	NA	NA	NA	-	-	-	-	0,7919
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Gender	Male	SVd Arm	115	50	43,48	65	56,52	17,28	4,04	NA	6,46	3,25	12,84	0,0000	0,7919
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Gender	Male	Vd Arm	113	10	8,85	103	91,15	NA	NA	NA	-	-	-	-	0,7919
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Age Group	<65	SVd Arm	86	41	47,67	45	52,33	NA	2,17	NA	5,53	2,57	11,92	0,0000	0,4790
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Age Group	<65	Vd Arm	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,4790
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Age Group	>=65	SVd Arm	109	55	50,46	54	49,54	4,47	2,10	NA	7,96	4,15	15,27	0,0000	0,4790
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Age Group	>=65	Vd Arm	129	13	10,08	116	89,92	NA	NA	NA	-	-	-	-	0,4790
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline R-ISS stage	Stage I or II	SVd Arm	173	86	49,71	87	50,29	6,01	2,79	NA	6,04	3,67	9,94	0,0000	0,8536
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline R-ISS stage	Stage I or II	Vd Arm	174	19	10,92	155	89,08	NA	NA	NA	-	-	-	-	0,8536
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	NA	1,05	NA	7,48	0,81	68,93	0,0452	0,8536
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,8536
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline ISS stage	Stage I or II	SVd Arm	163	89	54,60	74	45,40	3,94	2,00	NA	7,25	4,36	12,05	0,0000	0,5270
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline ISS stage	Stage I or II	Vd Arm	173	19	10,98	154	89,02	NA	NA	NA	-	-	-	-	0,5270
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline ISS stage	Stage III	SVd Arm	32	7	21,88	25	78,12	NA	NA	NA	4,25	0,88	20,56	0,0506	0,5270
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline ISS stage	Stage III	Vd Arm	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,5270
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (SAP)	Region 1	SVd Arm	18	13	72,22	5	27,78	0,10	0,07	NA	15,17	1,93	118,89	0,0007	0,6981
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,6981
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (SAP)	Region 2	SVd Arm	61	33	54,10	28	45,90	2,56	0,33	NA	5,21	2,46	11,00	0,0000	0,6981

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (SAP)	Region 2	Vd Arm	64	9	14,06	55	85,94	NA	NA	NA	-	-	-	-	0,6981
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (SAP)	Region 3	SVd Arm	47	17	36,17	30	63,83	NA	17,28	NA	10,12	2,32	44,03	0,0001	0,6981
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (SAP)	Region 3	Vd Arm	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,6981
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (SAP)	Region 4	SVd Arm	69	33	47,83	36	52,17	8,31	2,56	NA	5,57	2,56	12,11	0,0000	0,6981
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (SAP)	Region 4	Vd Arm	70	8	11,43	62	88,57	NA	32,53	NA	-	-	-	-	0,6981
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	56	47,86	61	52,14	8,31	3,94	NA	6,17	3,36	11,33	0,0000	0,9587
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,9587
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (by medical care situation)	Rest of the world	SVd Arm	78	40	51,28	38	48,72	3,35	1,64	NA	6,02	2,80	12,92	0,0000	0,9587
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Region (by medical care situation)	Rest of the world	Vd Arm	68	8	11,76	60	88,24	NA	32,53	NA	-	-	-	-	0,9587
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Race	Races other than White	SVd Arm	34	20	58,82	14	41,18	2,00	1,05	NA	11,01	3,58	33,90	0,0000	0,3769
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Race	Races other than White	Vd Arm	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,3769
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Race	White	SVd Arm	161	76	47,20	85	52,80	17,28	3,94	NA	6,27	3,64	10,80	0,0000	0,3769
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Race	White	Vd Arm	162	16	9,88	146	90,12	NA	NA	NA	-	-	-	-	0,3769
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	84	49,12	87	50,88	6,01	2,56	NA	6,34	3,84	10,46	0,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	20	10,81	165	89,19	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Prior PI therapies	N	SVd Arm	48	25	52,08	23	47,92	3,98	1,68	NA	6,68	2,53	17,62	0,0000	0,9274
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Prior PI therapies	N	Vd Arm	47	5	10,64	42	89,36	NA	32,53	NA	-	-	-	-	0,9274
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Prior PI therapies	Y	SVd Arm	147	71	48,30	76	51,70	8,31	2,79	NA	6,35	3,68	10,94	0,0000	0,9274
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Prior PI therapies	Y	Vd Arm	157	16	10,19	141	89,81	NA	NA	NA	-	-	-	-	0,9274
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Prior anti-MM regimen	>1	SVd Arm	98	48	48,98	50	51,02	8,31	2,10	NA	7,64	3,74	15,61	0,0000	0,5072

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Prior anti-MM regimen	>1	Vd Arm	104	9	8,65	95	91,35	NA	NA	NA	-	-	-	-	0,5072
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Prior anti-MM regimen	1	SVd Arm	97	48	49,48	49	50,52	4,60	2,99	NA	5,52	2,92	10,44	0,0000	0,5072
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Prior anti-MM regimen	1	Vd Arm	100	12	12,00	88	88,00	NA	NA	NA	-	-	-	-	0,5072
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline single cytogenetic alterations	N	SVd Arm	98	46	46,94	52	53,06	17,28	2,79	NA	5,12	2,80	9,39	0,0000	0,1833
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline single cytogenetic alterations	N	Vd Arm	111	14	12,61	97	87,39	NA	NA	NA	-	-	-	-	0,1833
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline single cytogenetic alterations	Y	SVd Arm	97	50	51,55	47	48,45	4,47	1,87	NA	10,41	4,45	24,38	0,0000	0,1833
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Baseline single cytogenetic alterations	Y	Vd Arm	93	7	7,53	86	92,47	NA	32,53	NA	-	-	-	-	0,1833
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Previously Exposed to Bortezomib	N	SVd Arm	61	31	50,82	30	49,18	4,04	1,68	NA	6,06	2,64	13,92	0,0000	0,8661
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Previously Exposed to Bortezomib	N	Vd Arm	62	7	11,29	55	88,71	NA	32,53	NA	-	-	-	-	0,8661
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Previously Exposed to Bortezomib	Y	SVd Arm	134	65	48,51	69	51,49	6,01	2,79	NA	6,62	3,70	11,83	0,0000	0,8661
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Nausea	Previously Exposed to Bortezomib	Y	Vd Arm	142	14	9,86	128	90,14	NA	NA	NA	-	-	-	-	0,8661
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	total	-	SVd Arm	195	39	20,00	~~156~~	~~80,00~~	~~NA~~	~~NA~~	~~NA~~	~~4,45~~	~~2,20~~	~~8,96~~	~~0,0000~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	total	-	Vd Arm	204	10	4,90	~~194~~	~~95,10~~	~~NA~~	~~NA~~	~~NA~~	~~-~~	~~-~~	~~-~~	~~-~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Gender	Female	SVd Arm	80	25	31,25	55	68,75	NA	NA	NA	7,96	2,74	23,07	0,0000	0,0530
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Gender	Female	Vd Arm	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,0530
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Gender	Male	SVd Arm	115	14	12,17	101	87,83	NA	NA	NA	1,91	0,72	5,07	0,1837	0,0530
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Gender	Male	Vd Arm	113	6	5,31	107	94,69	NA	NA	NA	-	-	-	-	0,0530
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Age Group	<65	SVd Arm	86	20	23,26	66	76,74	NA	NA	NA	6,93	2,03	23,64	0,0004	0,3303
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Age Group	<65	Vd Arm	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,3303
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Age Group	>=65	SVd Arm	109	19	17,43	90	82,57	NA	NA	NA	3,28	1,37	7,85	0,0048	0,3303
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Age Group	>=65	Vd Arm	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	0,3303
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline R-ISS stage	Stage I or II	SVd Arm	173	37	21,39	136	78,61	NA	NA	NA	5,07	2,36	10,89	0,0000	0,1205

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline R-ISS stage	Stage I or II	Vd Arm	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	0,1205
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	NA	NA	NA	0,59	0,04	7,96	0,6925	0,1205
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline R-ISS stage	Stage III	Vd Arm	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,1205
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline ISS stage	Stage I or II	SVd Arm	163	35	21,47	128	78,53	NA	NA	NA	4,50	2,16	9,37	0,0000	0,7435
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline ISS stage	Stage I or II	Vd Arm	173	9	5,20	164	94,80	NA	NA	NA	-	-	-	-	0,7435
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline ISS stage	Stage III	SVd Arm	32	4	12,50	28	87,50	NA	NA	NA	3,02	0,31	29,38	0,3174	0,7435
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,7435
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	NA	NA	NA	1,35	0,22	8,41	0,7447	0,4619
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,4619
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (SAP)	Region 2	SVd Arm	61	15	24,59	46	75,41	NA	NA	NA	5,48	1,58	19,01	0,0027	0,4619
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (SAP)	Region 2	Vd Arm	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,4619
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (SAP)	Region 3	SVd Arm	47	4	8,51	43	91,49	-	-	-	-	-	-	-	0,4619
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,4619
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (SAP)	Region 4	SVd Arm	69	17	24,64	52	75,36	NA	NA	NA	3,76	1,36	10,39	0,0062	0,4619
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (SAP)	Region 4	Vd Arm	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,4619
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	20	17,09	97	82,91	NA	NA	NA	4,83	1,80	12,99	0,0006	0,6441
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,6441
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (by medical care situation)	Rest of the world	SVd Arm	78	19	24,36	59	75,64	NA	NA	NA	3,47	1,28	9,44	0,0097	0,6441
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Region (by medical care situation)	Rest of the world	Vd Arm	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,6441
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Race	Races other than White	SVd Arm	34	13	38,24	21	61,76	NA	13,11	NA	2,86	1,04	7,86	0,0348	0,1312
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Race	Races other than White	Vd Arm	42	7	16,67	35	83,33	NA	NA	NA	-	-	-	-	0,1312
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Race	White	SVd Arm	161	26	16,15	135	83,85	NA	NA	NA	9,64	2,87	32,34	0,0000	0,1312

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Race	White	Vd Arm	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	0,1312
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	32	18,71	139	81,29	NA	NA	NA	4,58	2,09	10,02	0,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	8	4,32	177	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Prior PI therapies	N	SVd Arm	48	13	27,08	35	72,92	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Prior PI therapies	Y	SVd Arm	147	26	17,69	121	82,31	NA	NA	NA	2,93	1,41	6,09	0,0025	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Prior PI therapies	Y	Vd Arm	157	10	6,37	147	93,63	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Prior anti-MM regimen	>1	SVd Arm	98	23	23,47	75	76,53	NA	NA	NA	4,16	1,68	10,26	0,0008	0,8220
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Prior anti-MM regimen	>1	Vd Arm	104	6	5,77	98	94,23	NA	NA	NA	-	-	-	-	0,8220
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Prior anti-MM regimen	1	SVd Arm	97	16	16,49	81	83,51	NA	NA	NA	4,90	1,61	14,88	0,0020	0,8220
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Prior anti-MM regimen	1	Vd Arm	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,8220
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline single cytogenetic alterations	N	SVd Arm	98	21	21,43	77	78,57	NA	NA	NA	4,58	1,83	11,51	0,0004	0,8911
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline single cytogenetic alterations	N	Vd Arm	111	6	5,41	105	94,59	NA	NA	NA	-	-	-	-	0,8911
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline single cytogenetic alterations	Y	SVd Arm	97	18	18,56	79	81,44	NA	NA	NA	4,15	1,40	12,29	0,0053	0,8911
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Baseline single cytogenetic alterations	Y	Vd Arm	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,8911
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Previously Exposed to Bortezomib	N	SVd Arm	61	15	24,59	46	75,41	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Previously Exposed to Bortezomib	Y	SVd Arm	134	24	17,91	110	82,09	NA	NA	NA	2,78	1,32	5,83	0,0048	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Vomiting	Previously Exposed to Bortezomib	Y	Vd Arm	142	10	7,04	132	92,96	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	total	-	SVd Arm	195	68	34,87	~~127~~	~~65,13~~	~~NA~~	~~NA~~	~~NA~~	~~7,59~~	~~4,01~~	~~14,38~~	~~0,0000~~	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	total	-	Vd Arm	204	11	5,39	~~193~~	~~94,61~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Gender	Female	SVd Arm	80	32	40,00	48	60,00	NA	7,85	NA	13,24	4,03	43,52	0,0000	0,1963
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Gender	Female	Vd Arm	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,1963
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Gender	Male	SVd Arm	115	36	31,30	79	68,70	NA	NA	NA	5,19	2,40	11,25	0,0000	0,1963
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Gender	Male	Vd Arm	113	8	7,08	105	92,92	NA	NA	NA	-	-	-	-	0,1963
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Age Group	<65	SVd Arm	86	28	32,56	58	67,44	NA	NA	NA	3,45	1,55	7,68	0,0013	0,0185
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Age Group	<65	Vd Arm	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,0185
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Age Group	>=65	SVd Arm	109	40	36,70	69	63,30	NA	11,53	NA	19,09	5,89	61,93	0,0000	0,0185
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Age Group	>=65	Vd Arm	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	0,0185
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline R-ISS stage	Stage I or II	SVd Arm	173	59	34,10	114	65,90	NA	NA	NA	7,73	3,83	15,61	0,0000	0,7211
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline R-ISS stage	Stage I or II	Vd Arm	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	0,7211
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	NA	1,64	NA	5,05	0,54	47,17	0,1254	0,7211
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,7211
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline ISS stage	Stage I or II	SVd Arm	163	53	32,52	110	67,48	NA	NA	NA	8,22	3,90	17,31	0,0000	0,6862
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline ISS stage	Stage I or II	Vd Arm	173	8	4,62	165	95,38	NA	NA	NA	-	-	-	-	0,6862
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline ISS stage	Stage III	SVd Arm	32	15	46,88	17	53,12	5,59	2,56	NA	6,10	1,75	21,19	0,0012	0,6862
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline ISS stage	Stage III	Vd Arm	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,6862
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (SAP)	Region 1	SVd Arm	18	7	38,89	11	61,11	-	-	-	-	-	-	-	0,6324

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,6324
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (SAP)	Region 2	SVd Arm	61	27	44,26	34	55,74	7,85	2,63	NA	8,35	2,90	24,08	0,0000	0,6324
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (SAP)	Region 2	Vd Arm	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,6324
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (SAP)	Region 3	SVd Arm	47	11	23,40	36	76,60	NA	NA	NA	10,15	1,31	78,82	0,0062	0,6324
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (SAP)	Region 3	Vd Arm	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,6324
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (SAP)	Region 4	SVd Arm	69	23	33,33	46	66,67	NA	NA	NA	4,65	1,89	11,46	0,0002	0,6324
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (SAP)	Region 4	Vd Arm	70	6	8,57	64	91,43	NA	NA	NA	-	-	-	-	0,6324
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	38	32,48	79	67,52	NA	NA	NA	12,52	4,45	35,21	0,0000	0,1464
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	4	2,94	132	97,06	NA	NA	NA	-	-	-	-	0,1464
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (by medical care situation)	Rest of the world	SVd Arm	78	30	38,46	48	61,54	NA	4,63	NA	4,68	2,04	10,74	0,0001	0,1464
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Region (by medical care situation)	Rest of the world	Vd Arm	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,1464
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Race	Races other than White	SVd Arm	34	17	50,00	17	50,00	4,27	1,25	NA	3,70	1,51	9,07	0,0023	0,0255
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Race	Races other than White	Vd Arm	42	8	19,05	34	80,95	NA	21,52	NA	-	-	-	-	0,0255
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Race	White	SVd Arm	161	51	31,68	110	68,32	NA	NA	NA	19,79	6,16	63,54	0,0000	0,0255
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Race	White	Vd Arm	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	0,0255
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	54	31,58	117	68,42	NA	NA	NA	6,17	3,21	11,84	0,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	11	5,95	174	94,05	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Prior PI therapies	N	SVd Arm	48	19	39,58	29	60,42	NA	4,01	NA	11,48	2,66	49,49	0,0000	0,5197
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Prior PI therapies	N	Vd Arm	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,5197
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Prior PI therapies	Y	SVd Arm	147	49	33,33	98	66,67	NA	NA	NA	6,73	3,30	13,72	0,0000	0,5197
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Prior PI therapies	Y	Vd Arm	157	9	5,73	148	94,27	NA	NA	NA	-	-	-	-	0,5197
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Prior anti-MM regimen	>1	SVd Arm	98	35	35,71	63	64,29	NA	11,53	NA	5,37	2,49	11,60	0,0000	0,1999
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Prior anti-MM regimen	>1	Vd Arm	104	8	7,69	96	92,31	NA	NA	NA	-	-	-	-	0,1999
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Prior anti-MM regimen	1	SVd Arm	97	33	34,02	64	65,98	NA	NA	NA	13,53	4,14	44,20	0,0000	0,1999
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Prior anti-MM regimen	1	Vd Arm	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,1999
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline single cytogenetic alterations	N	SVd Arm	98	34	34,69	64	65,31	NA	NA	NA	6,23	2,86	13,60	0,0000	0,4162
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline single cytogenetic alterations	N	Vd Arm	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,4162
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline single cytogenetic alterations	Y	SVd Arm	97	34	35,05	63	64,95	NA	NA	NA	11,22	3,44	36,60	0,0000	0,4162
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Baseline single cytogenetic alterations	Y	Vd Arm	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,4162
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Previously Exposed to Bortezomib	N	SVd Arm	61	25	40,98	36	59,02	NA	3,48	NA	15,53	3,66	65,95	0,0000	0,2418
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,2418
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Previously Exposed to Bortezomib	Y	SVd Arm	134	43	32,09	91	67,91	NA	NA	NA	5,91	2,87	12,17	0,0000	0,2418
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Decreased Appetite	Previously Exposed to Bortezomib	Y	Vd Arm	142	9	6,34	133	93,66	NA	NA	NA	-	-	-	-	0,2418
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	total	-	SVd Arm	195	50	25,64	~~145~~	~~74,36~~	~~NA~~	~~NA~~	~~NA~~	~~2,68~~	~~1,62~~	~~4,41~~	~~0,0001~~	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	total	-	Vd Arm	204	23	11,27	~~181~~	~~88,73~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Gender	Female	SVd Arm	80	24	30,00	56	70,00	NA	NA	NA	8,47	2,90	24,72	0,0000	0,0046
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Gender	Female	Vd Arm	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,0046
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Gender	Male	SVd Arm	115	26	22,61	89	77,39	NA	NA	NA	1,43	0,79	2,61	0,2374	0,0046
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Gender	Male	Vd Arm	113	19	16,81	94	83,19	NA	NA	NA	-	-	-	-	0,0046
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Age Group	<65	SVd Arm	86	21	24,42	65	75,58	NA	NA	NA	2,08	0,93	4,65	0,0687	0,4917
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Age Group	<65	Vd Arm	75	9	12,00	66	88,00	NA	NA	NA	-	-	-	-	0,4917
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Age Group	>=65	SVd Arm	109	29	26,61	80	73,39	NA	NA	NA	2,99	1,57	5,72	0,0005	0,4917
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Age Group	>=65	Vd Arm	129	14	10,85	115	89,15	NA	NA	NA	-	-	-	-	0,4917
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline R-ISS stage	Stage I or II	SVd Arm	173	41	23,70	132	76,30	NA	NA	NA	2,85	1,60	5,09	0,0002	0,8044
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline R-ISS stage	Stage I or II	Vd Arm	174	16	9,20	158	90,80	NA	NA	NA	-	-	-	-	0,8044
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline R-ISS stage	Stage III	SVd Arm	12	7	58,33	5	41,67	3,02	1,64	NA	3,47	0,82	14,59	0,0772	0,8044
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline R-ISS stage	Stage III	Vd Arm	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,8044
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline ISS stage	Stage I or II	SVd Arm	163	38	23,31	125	76,69	NA	NA	NA	2,46	1,40	4,31	0,0012	0,6597
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline ISS stage	Stage I or II	Vd Arm	173	18	10,40	155	89,60	NA	NA	NA	-	-	-	-	0,6597
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline ISS stage	Stage III	SVd Arm	32	12	37,50	20	62,50	8,28	3,02	NA	3,22	1,11	9,28	0,0231	0,6597
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline ISS stage	Stage III	Vd Arm	31	5	16,13	26	83,87	NA	NA	NA	-	-	-	-	0,6597
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	NA	NA	NA	2,46	0,25	24,06	0,4241	0,9415

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,9415
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (SAP)	Region 2	SVd Arm	61	13	21,31	48	78,69	NA	NA	NA	2,35	0,89	6,22	0,0759	0,9415
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (SAP)	Region 2	Vd Arm	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,9415
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (SAP)	Region 3	SVd Arm	47	9	19,15	38	80,85	NA	NA	NA	4,17	0,89	19,50	0,0493	0,9415
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (SAP)	Region 3	Vd Arm	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,9415
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (SAP)	Region 4	SVd Arm	69	25	36,23	44	63,77	NA	7,98	NA	2,63	1,35	5,12	0,0033	0,9415
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (SAP)	Region 4	Vd Arm	70	14	20,00	56	80,00	NA	NA	NA	-	-	-	-	0,9415
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	23	19,66	94	80,34	NA	NA	NA	3,05	1,40	6,64	0,0032	0,7494
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	9	6,62	127	93,38	NA	NA	NA	-	-	-	-	0,7494
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (by medical care situation)	Rest of the world	SVd Arm	78	27	34,62	51	65,38	NA	7,98	NA	2,58	1,33	5,02	0,0038	0,7494
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Region (by medical care situation)	Rest of the world	Vd Arm	68	14	20,59	54	79,41	NA	NA	NA	-	-	-	-	0,7494
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Race	Races other than White	SVd Arm	34	14	41,18	20	58,82	8,28	4,04	NA	2,91	1,15	7,36	0,0184	0,9974
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Race	Races other than White	Vd Arm	42	9	21,43	33	78,57	NA	NA	NA	-	-	-	-	0,9974
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Race	White	SVd Arm	161	36	22,36	125	77,64	NA	NA	NA	2,92	1,55	5,48	0,0005	0,9974
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Race	White	Vd Arm	162	14	8,64	148	91,36	NA	NA	NA	-	-	-	-	0,9974
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	41	23,98	130	76,02	NA	NA	NA	2,48	1,46	4,24	0,0006	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	21	11,35	164	88,65	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Prior PI therapies	N	SVd Arm	48	10	20,83	38	79,17	NA	NA	NA	2,33	0,79	6,86	0,1156	0,7771
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Prior PI therapies	N	Vd Arm	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,7771
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Prior PI therapies	Y	SVd Arm	147	40	27,21	107	72,79	NA	NA	NA	2,77	1,58	4,87	0,0002	0,7771
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Prior PI therapies	Y	Vd Arm	157	18	11,46	139	88,54	NA	NA	NA	-	-	-	-	0,7771
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Prior anti-MM regimen	>1	SVd Arm	98	27	27,55	71	72,45	NA	NA	NA	2,74	1,40	5,36	0,0023	0,9189
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Prior anti-MM regimen	>1	Vd Arm	104	13	12,50	91	87,50	NA	NA	NA	-	-	-	-	0,9189
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Prior anti-MM regimen	1	SVd Arm	97	23	23,71	74	76,29	NA	NA	NA	2,60	1,23	5,48	0,0091	0,9189
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Prior anti-MM regimen	1	Vd Arm	100	10	10,00	90	90,00	NA	NA	NA	-	-	-	-	0,9189
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline single cytogenetic alterations	N	SVd Arm	98	25	25,51	73	74,49	NA	NA	NA	2,36	1,24	4,48	0,0071	0,5031
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline single cytogenetic alterations	N	Vd Arm	111	16	14,41	95	85,59	NA	NA	NA	-	-	-	-	0,5031
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline single cytogenetic alterations	Y	SVd Arm	97	25	25,77	72	74,23	NA	NA	NA	3,38	1,46	7,84	0,0025	0,5031
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Baseline single cytogenetic alterations	Y	Vd Arm	93	7	7,53	86	92,47	NA	NA	NA	-	-	-	-	0,5031
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Previously Exposed to Bortezomib	N	SVd Arm	61	13	21,31	48	78,69	NA	NA	NA	1,47	0,60	3,57	0,3933	0,1235
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Previously Exposed to Bortezomib	N	Vd Arm	62	9	14,52	53	85,48	NA	NA	NA	-	-	-	-	0,1235
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Previously Exposed to Bortezomib	Y	SVd Arm	134	37	27,61	97	72,39	NA	NA	NA	3,44	1,84	6,43	0,0000	0,1235
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Weight Decreased	Previously Exposed to Bortezomib	Y	Vd Arm	142	14	9,86	128	90,14	NA	NA	NA	-	-	-	-	0,1235
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	total	-	SVd Arm	195	15	7,69	~~180~~	~~92,31~~	~~NA~~	~~NA~~	~~NA~~	~~1,11~~	~~0,54~~	~~2,32~~	~~0,7714~~	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	total	-	Vd Arm	204	15	7,35	~~189~~	~~92,65~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Gender	Female	SVd Arm	80	4	5,00	76	95,00	NA	NA	NA	0,69	0,19	2,52	0,5699	0,4201
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Gender	Female	Vd Arm	91	7	7,69	84	92,31	NA	NA	NA	-	-	-	-	0,4201
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Gender	Male	SVd Arm	115	11	9,57	104	90,43	NA	NA	NA	1,32	0,53	3,31	0,5492	0,4201
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Gender	Male	Vd Arm	113	8	7,08	105	92,92	NA	NA	NA	-	-	-	-	0,4201
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Age Group	<65	SVd Arm	86	9	10,47	77	89,53	NA	NA	NA	1,06	0,39	2,89	0,9057	0,9250
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Age Group	<65	Vd Arm	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,9250
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Age Group	>=65	SVd Arm	109	6	5,50	103	94,50	NA	NA	NA	0,99	0,33	2,97	0,9845	0,9250
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Age Group	>=65	Vd Arm	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	0,9250
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	11	6,36	162	93,64	NA	NA	NA	0,79	0,35	1,77	0,5707	0,0701
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	13	7,47	161	92,53	NA	NA	NA	-	-	-	-	0,0701
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline R-ISS stage	Stage III	SVd Arm	12	4	33,33	8	66,67	NA	4,17	NA	7,16	0,76	67,41	0,0494	0,0701
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,0701
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline ISS stage	Stage I or II	SVd Arm	163	10	6,13	153	93,87	NA	NA	NA	0,76	0,33	1,73	0,5057	0,2018
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline ISS stage	Stage I or II	Vd Arm	173	13	7,51	160	92,49	NA	NA	NA	-	-	-	-	0,2018
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline ISS stage	Stage III	SVd Arm	32	5	15,62	27	84,38	NA	NA	NA	2,51	0,48	12,98	0,2570	0,2018
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline ISS stage	Stage III	Vd Arm	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,2018
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	NA	NA	NA	0,47	0,04	5,24	0,5337	0,4372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,4372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (SAP)	Region 2	SVd Arm	61	4	6,56	57	93,44	NA	NA	NA	0,98	0,24	4,01	0,9747	0,4372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (SAP)	Region 2	Vd Arm	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,4372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (SAP)	Region 3	SVd Arm	47	1	2,13	46	97,87	NA	NA	NA	0,24	0,02	2,86	0,2272	0,4372

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (SAP)	Region 3	Vd Arm	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,4372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (SAP)	Region 4	SVd Arm	69	9	13,04	60	86,96	NA	NA	NA	1,75	0,62	4,93	0,2861	0,4372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (SAP)	Region 4	Vd Arm	70	6	8,57	64	91,43	NA	NA	NA	-	-	-	-	0,4372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	5	4,27	112	95,73	NA	NA	NA	0,76	0,23	2,44	0,6394	0,4071
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	8	5,88	128	94,12	NA	NA	NA	-	-	-	-	0,4071
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (by medical care situation)	Rest of the world	SVd Arm	78	10	12,82	68	87,18	NA	NA	NA	1,44	0,54	3,82	0,4604	0,4071
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Region (by medical care situation)	Rest of the world	Vd Arm	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,4071
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	0,79	0,13	4,93	0,7964	0,6765
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Race	Races other than White	Vd Arm	42	3	7,14	39	92,86	NA	NA	NA	-	-	-	-	0,6765
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Race	White	SVd Arm	161	13	8,07	148	91,93	NA	NA	NA	1,21	0,53	2,73	0,6534	0,6765
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Race	White	Vd Arm	162	12	7,41	150	92,59	NA	NA	NA	-	-	-	-	0,6765
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	13	7,60	158	92,40	NA	NA	NA	1,08	0,50	2,33	0,8506	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	14	7,57	171	92,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Prior PI therapies	N	SVd Arm	48	2	4,17	46	95,83	NA	NA	NA	0,47	0,09	2,58	0,3752	0,2629
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Prior PI therapies	N	Vd Arm	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,2629
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Prior PI therapies	Y	SVd Arm	147	13	8,84	134	91,16	NA	NA	NA	1,39	0,61	3,18	0,4347	0,2629
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Prior PI therapies	Y	Vd Arm	157	10	6,37	147	93,63	NA	NA	NA	-	-	-	-	0,2629
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Prior anti-MM regimen	>1	SVd Arm	98	8	8,16	90	91,84	NA	NA	NA	1,03	0,39	2,75	0,9540	0,8127
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Prior anti-MM regimen	>1	Vd Arm	104	8	7,69	96	92,31	NA	NA	NA	-	-	-	-	0,8127
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Prior anti-MM regimen	1	SVd Arm	97	7	7,22	90	92,78	NA	NA	NA	1,23	0,41	3,68	0,7111	0,8127

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Prior anti-MM regimen	1	Vd Arm	100	7	7,00	93	93,00	NA	NA	NA	-	-	-	-	0,8127
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline single cytogenetic alterations	N	SVd Arm	98	6	6,12	92	93,88	NA	NA	NA	0,79	0,28	2,24	0,6584	0,3593
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline single cytogenetic alterations	N	Vd Arm	111	9	8,11	102	91,89	NA	NA	NA	-	-	-	-	0,3593
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline single cytogenetic alterations	Y	SVd Arm	97	9	9,28	88	90,72	NA	NA	NA	1,61	0,53	4,87	0,3950	0,3593
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Baseline single cytogenetic alterations	Y	Vd Arm	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,3593
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Previously Exposed to Bortezomib	N	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	0,47	0,09	2,58	0,3752	0,2394
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Previously Exposed to Bortezomib	N	Vd Arm	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,2394
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Previously Exposed to Bortezomib	Y	SVd Arm	134	13	9,70	121	90,30	NA	NA	NA	1,47	0,64	3,37	0,3617	0,2394
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Pneumonia	Previously Exposed to Bortezomib	Y	Vd Arm	142	10	7,04	132	92,96	NA	NA	NA	-	-	-	-	0,2394
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	total	-	SVd Arm	195	0	0,00	~~195~~	~~100,00~~	~~NA~~	~~NA~~	~~NA~~	~~NA~~	~~NA~~	~~NA~~	~~1,0000~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	total	-	Vd Arm	204	0	0,00	~~204~~	~~100,00~~	~~NA~~	~~NA~~	~~NA~~	~~-~~	~~-~~	~~-~~	~~-~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Gender	Female	SVd Arm	80	0	0,00	80	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Gender	Female	Vd Arm	91	0	0,00	91	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Gender	Male	SVd Arm	115	0	0,00	115	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Gender	Male	Vd Arm	113	0	0,00	113	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Age Group	<65	SVd Arm	86	0	0,00	86	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Age Group	>=65	SVd Arm	109	0	0,00	109	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline R-ISS stage	Stage I or II	SVd Arm	173	0	0,00	173	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline ISS stage	Stage I or II	SVd Arm	163	0	0,00	163	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (SAP)	Region 2	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (SAP)	Region 4	SVd Arm	69	0	0,00	69	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	0	0,00	117	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (by medical care situation)	Rest of the world	SVd Arm	78	0	0,00	78	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Race	White	SVd Arm	161	0	0,00	161	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Race	White	Vd Arm	162	0	0,00	162	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	0	0,00	171	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Prior PI therapies	Y	SVd Arm	147	0	0,00	147	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Prior anti-MM regimen	>1	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Prior anti-MM regimen	1	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline single cytogenetic alterations	N	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline single cytogenetic alterations	Y	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Previously Exposed to Bortezomib	N	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Previously Exposed to Bortezomib	Y	SVd Arm	134	0	0,00	134	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Sepsis	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	total	-	SVd Arm	195	12	6,15	~~183~~	~~93,85~~	~~NA~~	~~NA~~	~~NA~~	~~1,34~~	~~0,56~~	~~3,18~~	~~0,5103~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	total	-	Vd Arm	204	9	4,41	~~195~~	~~95,59~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Gender	Female	SVd Arm	80	5	6,25	75	93,75	NA	NA	NA	2,87	0,55	14,99	0,1923	0,2743

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Gender	Female	Vd Arm	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,2743
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Gender	Male	SVd Arm	115	7	6,09	108	93,91	NA	NA	NA	0,96	0,33	2,76	0,9398	0,2743
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Gender	Male	Vd Arm	113	7	6,19	106	93,81	NA	NA	NA	-	-	-	-	0,2743
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Age Group	<65	SVd Arm	86	9	10,47	77	89,53	NA	NA	NA	1,64	0,50	5,41	0,4111	0,3346
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Age Group	<65	Vd Arm	75	4	5,33	71	94,67	NA	NA	NA	-	-	-	-	0,3346
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	NA	NA	NA	0,65	0,15	2,76	0,5599	0,3346
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Age Group	>=65	Vd Arm	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,3346
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline R-ISS stage	Stage I or II	SVd Arm	173	11	6,36	162	93,64	NA	NA	NA	1,35	0,54	3,37	0,5215	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline R-ISS stage	Stage I or II	Vd Arm	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline ISS stage	Stage I or II	SVd Arm	163	11	6,75	152	93,25	NA	NA	NA	1,44	0,58	3,58	0,4352	0,9950
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline ISS stage	Stage I or II	Vd Arm	173	8	4,62	165	95,38	NA	NA	NA	-	-	-	-	0,9950
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	NA	NA	NA	1,45	0,08	25,07	0,7977	0,9950
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,9950
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,1194
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,1194
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (SAP)	Region 2	SVd Arm	61	7	11,48	54	88,52	NA	NA	NA	7,64	0,94	62,22	0,0249	0,1194

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (SAP)	Region 2	Vd Arm	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,1194
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (SAP)	Region 3	SVd Arm	47	2	4,26	45	95,74	NA	NA	NA	0,75	0,10	5,42	0,7758	0,1194
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (SAP)	Region 3	Vd Arm	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,1194
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (SAP)	Region 4	SVd Arm	69	3	4,35	66	95,65	NA	NA	NA	0,57	0,13	2,38	0,4304	0,1194
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (SAP)	Region 4	Vd Arm	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,1194
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	7	5,98	110	94,02	NA	NA	NA	1,58	0,50	5,03	0,4315	0,6166
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,6166
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (by medical care situation)	Rest of the world	SVd Arm	78	5	6,41	73	93,59	NA	NA	NA	1,01	0,27	3,78	0,9860	0,6166
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Region (by medical care situation)	Rest of the world	Vd Arm	68	4	5,88	64	94,12	NA	NA	NA	-	-	-	-	0,6166
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	2,40	0,18	31,81	0,4968	0,6082
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,6082
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Race	White	SVd Arm	161	10	6,21	151	93,79	NA	NA	NA	1,17	0,46	2,99	0,7398	0,6082
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Race	White	Vd Arm	162	8	4,94	154	95,06	NA	NA	NA	-	-	-	-	0,6082
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	10	5,85	161	94,15	NA	NA	NA	1,17	0,47	2,90	0,7279	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	9	4,86	176	95,14	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Prior PI therapies	N	SVd Arm	48	3	6,25	45	93,75	NA	NA	NA	0,68	0,15	3,05	0,6136	0,2797

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Prior PI therapies	N	Vd Arm	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,2797
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Prior PI therapies	Y	SVd Arm	147	9	6,12	138	93,88	NA	NA	NA	1,90	0,63	5,68	0,2444	0,2797
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Prior PI therapies	Y	Vd Arm	157	5	3,18	152	96,82	NA	NA	NA	-	-	-	-	0,2797
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Prior anti-MM regimen	>1	SVd Arm	98	4	4,08	94	95,92	NA	NA	NA	0,61	0,17	2,18	0,4463	0,0982
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Prior anti-MM regimen	>1	Vd Arm	104	6	5,77	98	94,23	NA	NA	NA	-	-	-	-	0,0982
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Prior anti-MM regimen	1	SVd Arm	97	8	8,25	89	91,75	NA	NA	NA	2,89	0,76	10,95	0,1013	0,0982
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Prior anti-MM regimen	1	Vd Arm	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,0982
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	0,76	0,17	3,42	0,7151	0,3923
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline single cytogenetic alterations	N	Vd Arm	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,3923
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline single cytogenetic alterations	Y	SVd Arm	97	9	9,28	88	90,72	NA	NA	NA	1,71	0,57	5,12	0,3344	0,3923
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Baseline single cytogenetic alterations	Y	Vd Arm	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,3923
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Previously Exposed to Bortezomib	N	SVd Arm	61	4	6,56	57	93,44	NA	NA	NA	0,86	0,23	3,25	0,8217	0,3407
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Previously Exposed to Bortezomib	N	Vd Arm	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,3407
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Previously Exposed to Bortezomib	Y	SVd Arm	134	8	5,97	126	94,03	NA	NA	NA	2,05	0,62	6,83	0,2312	0,3407
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Opportunistic Infection	Previously Exposed to Bortezomib	Y	Vd Arm	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,3407
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	total	-	SVd Arm	195	26	13,33	~~169~~	~~86,67~~	~~NA~~	~~NA~~	~~NA~~	~~1,85~~	~~0,97~~	~~3,50~~	~~0,0569~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	total	-	Vd Arm	204	15	7,35	~~189~~	~~92,65~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Gender	Female	SVd Arm	80	9	11,25	71	88,75	NA	NA	NA	1,20	0,41	3,50	0,7446	0,3749

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Gender	Female	Vd Arm	91	6	6,59	85	93,41	NA	NA	NA	-	-	-	-	0,3749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Gender	Male	SVd Arm	115	17	14,78	98	85,22	NA	NA	NA	2,21	0,97	5,05	0,0550	0,3749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Gender	Male	Vd Arm	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	0,3749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Age Group	<65	SVd Arm	86	11	12,79	75	87,21	NA	NA	NA	0,84	0,34	2,06	0,6958	0,0482
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Age Group	<65	Vd Arm	75	9	12,00	66	88,00	NA	NA	NA	-	-	-	-	0,0482
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Age Group	>=65	SVd Arm	109	15	13,76	94	86,24	NA	NA	NA	3,15	1,21	8,20	0,0135	0,0482
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Age Group	>=65	Vd Arm	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	0,0482
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline R-ISS stage	Stage I or II	SVd Arm	173	24	13,87	149	86,13	NA	NA	NA	2,21	1,08	4,52	0,0267	0,5363
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline R-ISS stage	Stage I or II	Vd Arm	174	11	6,32	163	93,68	NA	NA	NA	-	-	-	-	0,5363
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	NA	NA	NA	0,87	0,05	15,38	0,9219	0,5363
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline R-ISS stage	Stage III	Vd Arm	16	2	12,50	14	87,50	NA	19,12	NA	-	-	-	-	0,5363
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline ISS stage	Stage I or II	SVd Arm	163	24	14,72	139	85,28	NA	NA	NA	2,12	1,06	4,24	0,0304	0,5003
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline ISS stage	Stage I or II	Vd Arm	173	12	6,94	161	93,06	NA	NA	NA	-	-	-	-	0,5003
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	NA	NA	NA	1,03	0,15	7,36	0,9729	0,5003
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline ISS stage	Stage III	Vd Arm	31	3	9,68	28	90,32	NA	19,12	NA	-	-	-	-	0,5003
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (SAP)	Region 1	SVd Arm	18	5	27,78	13	72,22	30,03	NA	NA	2,46	0,42	14,26	0,3033	0,3412
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,3412
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (SAP)	Region 2	SVd Arm	61	12	19,67	49	80,33	NA	NA	NA	2,16	0,81	5,79	0,1150	0,3412

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (SAP)	Region 2	Vd Arm	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,3412
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (SAP)	Region 3	SVd Arm	47	5	10,64	42	89,36	-	-	-	-	-	-	-	0,3412
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,3412
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (SAP)	Region 4	SVd Arm	69	4	5,80	65	94,20	NA	NA	NA	0,72	0,20	2,52	0,6038	0,3412
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (SAP)	Region 4	Vd Arm	70	7	10,00	63	90,00	NA	NA	NA	-	-	-	-	0,3412
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	20	17,09	97	82,91	NA	NA	NA	2,81	1,23	6,41	0,0104	0,0901
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	8	5,88	128	94,12	NA	NA	NA	-	-	-	-	0,0901
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (by medical care situation)	Rest of the world	SVd Arm	78	6	7,69	72	92,31	NA	NA	NA	0,85	0,28	2,58	0,7718	0,0901
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Region (by medical care situation)	Rest of the world	Vd Arm	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,0901
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	0,88	0,15	4,99	0,8824	0,3233
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Race	Races other than White	Vd Arm	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,3233
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Race	White	SVd Arm	161	24	14,91	137	85,09	NA	NA	NA	2,27	1,08	4,78	0,0260	0,3233
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Race	White	Vd Arm	162	10	6,17	152	93,83	NA	NA	NA	-	-	-	-	0,3233
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	24	14,04	147	85,96	NA	NA	NA	1,96	1,01	3,82	0,0443	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	14	7,57	171	92,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Prior PI therapies	N	SVd Arm	48	6	12,50	42	87,50	NA	NA	NA	1,88	0,46	7,69	0,3722	0,9762

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Prior PI therapies	N	Vd Arm	47	3	6,38	44	93,62	NA	26,71	NA	-	-	-	-	0,9762
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Prior PI therapies	Y	SVd Arm	147	20	13,61	127	86,39	NA	NA	NA	1,84	0,89	3,77	0,0926	0,9762
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Prior PI therapies	Y	Vd Arm	157	12	7,64	145	92,36	NA	NA	NA	-	-	-	-	0,9762
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Prior anti-MM regimen	>1	SVd Arm	98	8	8,16	90	91,84	NA	NA	NA	0,79	0,31	2,02	0,6264	0,0189
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Prior anti-MM regimen	>1	Vd Arm	104	10	9,62	94	90,38	NA	NA	NA	-	-	-	-	0,0189
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Prior anti-MM regimen	1	SVd Arm	97	18	18,56	79	81,44	NA	30,03	NA	4,08	1,50	11,06	0,0029	0,0189
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Prior anti-MM regimen	1	Vd Arm	100	5	5,00	95	95,00	NA	NA	NA	-	-	-	-	0,0189
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline single cytogenetic alterations	N	SVd Arm	98	10	10,20	88	89,80	NA	NA	NA	1,41	0,56	3,54	0,4649	0,3701
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline single cytogenetic alterations	N	Vd Arm	111	9	8,11	102	91,89	NA	NA	NA	-	-	-	-	0,3701
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline single cytogenetic alterations	Y	SVd Arm	97	16	16,49	81	83,51	NA	NA	NA	2,58	1,00	6,62	0,0417	0,3701
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Baseline single cytogenetic alterations	Y	Vd Arm	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,3701
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Previously Exposed to Bortezomib	N	SVd Arm	61	7	11,48	54	88,52	NA	NA	NA	1,83	0,52	6,39	0,3386	0,9683
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Previously Exposed to Bortezomib	N	Vd Arm	62	4	6,45	58	93,55	NA	26,71	NA	-	-	-	-	0,9683
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Previously Exposed to Bortezomib	Y	SVd Arm	134	19	14,18	115	85,82	NA	NA	NA	1,88	0,89	3,97	0,0914	0,9683
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Blurred Vision	Previously Exposed to Bortezomib	Y	Vd Arm	142	11	7,75	131	92,25	NA	NA	NA	-	-	-	-	0,9683
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	total	-	SVd Arm	195	29	14,87	~~166~~	~~85,13~~	~~NA~~	~~NA~~	~~NA~~	~~2,41~~	~~1,22~~	~~4,74~~	~~0,0089~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	total	-	Vd Arm	204	12	5,88	~~192~~	~~94,12~~	~~NA~~	~~41,20~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Gender	Female	SVd Arm	80	16	20,00	64	80,00	NA	16,99	NA	4,62	1,31	16,24	0,0095	0,1985
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Gender	Female	Vd Arm	91	4	4,40	87	95,60	NA	41,20	NA	-	-	-	-	0,1985

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Gender	Male	SVd Arm	115	13	11,30	102	88,70	NA	NA	NA	1,68	0,69	4,09	0,2473	0,1985
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Gender	Male	Vd Arm	113	8	7,08	105	92,92	NA	NA	NA	-	-	-	-	0,1985
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Age Group	<65	SVd Arm	86	18	20,93	68	79,07	NA	17,41	NA	4,15	1,36	12,65	0,0072	0,2107
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Age Group	<65	Vd Arm	75	5	6,67	70	93,33	41,20	41,20	NA	-	-	-	-	0,2107
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Age Group	>=65	SVd Arm	109	11	10,09	98	89,91	NA	NA	NA	1,62	0,62	4,25	0,3189	0,2107
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Age Group	>=65	Vd Arm	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	0,2107
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline R-ISS stage	Stage I or II	SVd Arm	173	24	13,87	149	86,13	NA	NA	NA	2,15	1,02	4,53	0,0390	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline R-ISS stage	Stage I or II	Vd Arm	174	10	5,75	164	94,25	41,20	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline R-ISS stage	Stage III	SVd Arm	12	3	25,00	9	75,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline ISS stage	Stage I or II	SVd Arm	163	25	15,34	138	84,66	NA	NA	NA	2,27	1,11	4,63	0,0207	0,4355
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline ISS stage	Stage I or II	Vd Arm	173	11	6,36	162	93,64	NA	41,20	NA	-	-	-	-	0,4355
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline ISS stage	Stage III	SVd Arm	32	4	12,50	28	87,50	NA	NA	NA	5,70	0,63	51,70	0,0817	0,4355
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,4355
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	NA	NA	NA	1,41	0,08	23,57	0,8084	0,4424
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,4424
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (SAP)	Region 2	SVd Arm	61	7	11,48	54	88,52	NA	NA	NA	1,59	0,52	4,81	0,4104	0,4424
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (SAP)	Region 2	Vd Arm	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,4424
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (SAP)	Region 3	SVd Arm	47	6	12,77	41	87,23	-	-	-	-	-	-	-	0,4424
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,4424
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (SAP)	Region 4	SVd Arm	69	15	21,74	54	78,26	NA	16,99	NA	4,19	1,38	12,75	0,0063	0,4424
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (SAP)	Region 4	Vd Arm	70	5	7,14	65	92,86	41,20	NA	NA	-	-	-	-	0,4424

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	13	11,11	104	88,89	NA	NA	NA	2,04	0,77	5,44	0,1446	0,4640
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	6	4,41	130	95,59	NA	NA	NA	-	-	-	-	0,4640
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (by medical care situation)	Rest of the world	SVd Arm	78	16	20,51	62	79,49	NA	16,99	NA	3,46	1,25	9,53	0,0109	0,4640
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Region (by medical care situation)	Rest of the world	Vd Arm	68	6	8,82	62	91,18	41,20	NA	NA	-	-	-	-	0,4640
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Race	Races other than White	SVd Arm	34	7	20,59	27	79,41	NA	8,90	NA	5,30	1,02	27,62	0,0297	0,2833
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Race	Races other than White	Vd Arm	42	3	7,14	39	92,86	NA	23,13	NA	-	-	-	-	0,2833
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Race	White	SVd Arm	161	22	13,66	139	86,34	NA	NA	NA	1,95	0,89	4,28	0,0912	0,2833
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Race	White	Vd Arm	162	9	5,56	153	94,44	NA	41,20	NA	-	-	-	-	0,2833
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	26	15,20	145	84,80	NA	NA	NA	2,94	1,37	6,32	0,0038	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	9	4,86	176	95,14	NA	41,20	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Prior PI therapies	N	SVd Arm	48	8	16,67	40	83,33	NA	16,99	NA	1,25	0,41	3,88	0,6938	0,1807
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Prior PI therapies	N	Vd Arm	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,1807
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Prior PI therapies	Y	SVd Arm	147	21	14,29	126	85,71	NA	NA	NA	3,31	1,40	7,81	0,0039	0,1807
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Prior PI therapies	Y	Vd Arm	157	7	4,46	150	95,54	NA	41,20	NA	-	-	-	-	0,1807
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Prior anti-MM regimen	>1	SVd Arm	98	17	17,35	81	82,65	NA	17,41	NA	3,03	1,19	7,73	0,0144	0,4522
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Prior anti-MM regimen	>1	Vd Arm	104	6	5,77	98	94,23	41,20	NA	NA	-	-	-	-	0,4522
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Prior anti-MM regimen	1	SVd Arm	97	12	12,37	85	87,63	NA	NA	NA	1,80	0,67	4,86	0,2402	0,4522
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Prior anti-MM regimen	1	Vd Arm	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,4522
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline single cytogenetic alterations	N	SVd Arm	98	16	16,33	82	83,67	NA	NA	NA	2,42	1,02	5,76	0,0393	0,9790
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline single cytogenetic alterations	N	Vd Arm	111	8	7,21	103	92,79	NA	41,20	NA	-	-	-	-	0,9790

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline single cytogenetic alterations	Y	SVd Arm	97	13	13,40	84	86,60	NA	NA	NA	2,38	0,77	7,36	0,1224	0,9790
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Baseline single cytogenetic alterations	Y	Vd Arm	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,9790
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Previously Exposed to Bortezomib	N	SVd Arm	61	10	16,39	51	83,61	NA	16,99	NA	1,44	0,48	4,28	0,5117	0,2840
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Previously Exposed to Bortezomib	N	Vd Arm	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,2840
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Previously Exposed to Bortezomib	Y	SVd Arm	134	19	14,18	115	85,82	NA	NA	NA	3,09	1,29	7,38	0,0078	0,2840
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cataract	Previously Exposed to Bortezomib	Y	Vd Arm	142	7	4,93	135	95,07	41,20	41,20	NA	-	-	-	-	0,2840
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	total	-	SVd Arm	195	9	4,62	~~186~~	~~95,38~~	~~NA~~	~~NA~~	~~NA~~	~~5,24~~	~~1,13~~	~~24,29~~	~~0,0181~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	total	-	Vd Arm	204	2	0,98	~~202~~	~~99,02~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Gender	Female	SVd Arm	80	4	5,00	76	95,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Gender	Male	SVd Arm	115	5	4,35	110	95,65	NA	NA	NA	2,44	0,47	12,68	0,2736	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Gender	Male	Vd Arm	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Age Group	<65	SVd Arm	86	4	4,65	82	95,35	NA	NA	NA	1,53	0,27	8,61	0,6304	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Age Group	<65	Vd Arm	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Age Group	>=65	SVd Arm	109	5	4,59	104	95,41	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	6	3,47	167	96,53	NA	NA	NA	3,34	0,67	16,55	0,1176	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline R-ISS stage	Stage III	SVd Arm	12	3	25,00	9	75,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline ISS stage	Stage I or II	SVd Arm	163	5	3,07	158	96,93	NA	NA	NA	2,86	0,55	14,74	0,1888	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline ISS stage	Stage I or II	Vd Arm	173	2	1,16	171	98,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline ISS stage	Stage III	SVd Arm	32	4	12,50	28	87,50	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,7633
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,7633
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (SAP)	Region 2	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	3,41	0,29	39,55	0,3012	0,7633
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (SAP)	Region 2	Vd Arm	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,7633
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (SAP)	Region 3	SVd Arm	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,7633
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,7633
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (SAP)	Region 4	SVd Arm	69	5	7,25	64	92,75	NA	NA	NA	5,62	0,65	48,31	0,0763	0,7633
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (SAP)	Region 4	Vd Arm	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,7633
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	NA	NA	NA	5,32	0,59	48,23	0,0975	0,9484
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,9484
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (by medical care situation)	Rest of the world	SVd Arm	78	5	6,41	73	93,59	NA	NA	NA	4,81	0,56	41,30	0,1142	0,9484
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Region (by medical care situation)	Rest of the world	Vd Arm	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,9484
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Race	Races other than White	SVd Arm	34	3	8,82	31	91,18	NA	NA	NA	2,94	0,29	29,88	0,3415	0,5861

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,5861
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Race	White	SVd Arm	161	6	3,73	155	96,27	NA	NA	NA	7,05	0,85	58,75	0,0357	0,5861
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Race	White	Vd Arm	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	0,5861
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	7	4,09	164	95,91	NA	NA	NA	4,22	0,88	20,38	0,0509	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	NA	NA	NA	1,09	0,07	17,49	0,9495	0,2227
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,2227
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Prior PI therapies	Y	SVd Arm	147	8	5,44	139	94,56	NA	NA	NA	9,45	1,18	75,73	0,0097	0,2227
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,2227
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Prior anti-MM regimen	>1	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	3,56	0,37	34,25	0,2408	0,6744
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Prior anti-MM regimen	>1	Vd Arm	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	0,6744
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Prior anti-MM regimen	1	SVd Arm	97	6	6,19	91	93,81	NA	NA	NA	6,92	0,83	57,61	0,0378	0,6744
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,6744
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline single cytogenetic alterations	N	SVd Arm	98	4	4,08	94	95,92	NA	NA	NA	4,99	0,56	44,93	0,1114	0,9903
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline single cytogenetic alterations	N	Vd Arm	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	0,9903
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline single cytogenetic alterations	Y	SVd Arm	97	5	5,15	92	94,85	NA	NA	NA	4,90	0,57	42,15	0,1092	0,9903

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,9903
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	NA	NA	NA	1,09	0,07	17,49	0,9495	0,2210
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,2210
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Previously Exposed to Bortezomib	Y	SVd Arm	134	8	5,97	126	94,03	NA	NA	NA	9,53	1,19	76,54	0,0095	0,2210
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hyponatraemia	Previously Exposed to Bortezomib	Y	Vd Arm	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	0,2210
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	total	-	SVd Arm	195	42	21,54	~~153~~	~~78,46~~	~~NA~~	~~NA~~	~~NA~~	~~2,87~~	~~1,61~~	~~5,11~~	~~0,0002~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	total	-	Vd Arm	204	16	7,84	~~188~~	~~92,16~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Gender	Female	SVd Arm	80	20	25,00	60	75,00	NA	NA	NA	4,21	1,56	11,33	0,0021	0,3225
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Gender	Female	Vd Arm	91	5	5,49	86	94,51	NA	NA	NA	-	-	-	-	0,3225
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Gender	Male	SVd Arm	115	22	19,13	93	80,87	NA	NA	NA	2,26	1,08	4,71	0,0262	0,3225
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Gender	Male	Vd Arm	113	11	9,73	102	90,27	NA	NA	NA	-	-	-	-	0,3225
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Age Group	<65	SVd Arm	86	8	9,30	78	90,70	NA	NA	NA	1,31	0,42	4,12	0,6403	0,0750
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Age Group	<65	Vd Arm	75	5	6,67	70	93,33	NA	NA	NA	-	-	-	-	0,0750
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Age Group	>=65	SVd Arm	109	34	31,19	75	68,81	NA	15,44	NA	4,41	2,22	8,77	0,0000	0,0750
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Age Group	>=65	Vd Arm	129	11	8,53	118	91,47	NA	NA	NA	-	-	-	-	0,0750
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline R-ISS stage	Stage I or II	SVd Arm	173	38	21,97	135	78,03	NA	NA	NA	3,11	1,65	5,86	0,0002	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline R-ISS stage	Stage I or II	Vd Arm	174	13	7,47	161	92,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline ISS stage	Stage I or II	SVd Arm	163	39	23,93	124	76,07	NA	NA	NA	3,39	1,81	6,37	0,0001	0,1572
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline ISS stage	Stage I or II	Vd Arm	173	13	7,51	160	92,49	NA	NA	NA	-	-	-	-	0,1572
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline ISS stage	Stage III	SVd Arm	32	3	9,38	29	90,62	NA	NA	NA	0,98	0,20	4,87	0,9762	0,1572
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline ISS stage	Stage III	Vd Arm	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,1572
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (SAP)	Region 1	SVd Arm	18	8	44,44	10	55,56	NA	2,66	NA	1,70	0,42	6,97	0,4531	0,0749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (SAP)	Region 1	Vd Arm	17	4	23,53	13	76,47	21,75	NA	NA	-	-	-	-	0,0749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (SAP)	Region 2	SVd Arm	61	25	40,98	36	59,02	15,44	6,14	NA	6,99	2,63	18,60	0,0000	0,0749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (SAP)	Region 2	Vd Arm	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,0749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (SAP)	Region 3	SVd Arm	47	3	6,38	44	93,62	NA	NA	NA	1,51	0,15	15,59	0,7274	0,0749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (SAP)	Region 3	Vd Arm	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,0749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (SAP)	Region 4	SVd Arm	69	6	8,70	63	91,30	NA	NA	NA	1,05	0,34	3,28	0,9267	0,0749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (SAP)	Region 4	Vd Arm	70	6	8,57	64	91,43	NA	NA	NA	-	-	-	-	0,0749
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	30	25,64	87	74,36	NA	NA	NA	3,31	1,64	6,68	0,0004	0,6457
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	11	8,09	125	91,91	NA	NA	NA	-	-	-	-	0,6457
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (by medical care situation)	Rest of the world	SVd Arm	78	12	15,38	66	84,62	NA	NA	NA	2,46	0,86	7,02	0,0827	0,6457
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Region (by medical care situation)	Rest of the world	Vd Arm	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,6457
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Race	Races other than White	SVd Arm	34	6	17,65	28	82,35	NA	NA	NA	1,62	0,45	5,88	0,4571	0,3045

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Race	Races other than White	Vd Arm	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,3045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Race	White	SVd Arm	161	36	22,36	125	77,64	NA	NA	NA	3,48	1,76	6,88	0,0001	0,3045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Race	White	Vd Arm	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	0,3045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	35	20,47	136	79,53	NA	NA	NA	2,49	1,37	4,52	0,0019	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	16	8,65	169	91,35	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Prior PI therapies	N	SVd Arm	48	13	27,08	35	72,92	NA	NA	NA	3,33	1,08	10,29	0,0266	0,7558
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Prior PI therapies	N	Vd Arm	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,7558
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Prior PI therapies	Y	SVd Arm	147	29	19,73	118	80,27	NA	NA	NA	2,71	1,38	5,31	0,0026	0,7558
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Prior PI therapies	Y	Vd Arm	157	12	7,64	145	92,36	NA	NA	NA	-	-	-	-	0,7558
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Prior anti-MM regimen	>1	SVd Arm	98	19	19,39	79	80,61	NA	NA	NA	4,17	1,55	11,17	0,0021	0,3308
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Prior anti-MM regimen	>1	Vd Arm	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,3308
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Prior anti-MM regimen	1	SVd Arm	97	23	23,71	74	76,29	NA	NA	NA	2,27	1,10	4,68	0,0225	0,3308
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Prior anti-MM regimen	1	Vd Arm	100	11	11,00	89	89,00	NA	NA	NA	-	-	-	-	0,3308
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline single cytogenetic alterations	N	SVd Arm	98	20	20,41	78	79,59	NA	NA	NA	4,05	1,67	9,84	0,0009	0,3464
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline single cytogenetic alterations	N	Vd Arm	111	7	6,31	104	93,69	NA	NA	NA	-	-	-	-	0,3464
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline single cytogenetic alterations	Y	SVd Arm	97	22	22,68	75	77,32	NA	NA	NA	2,30	1,05	5,00	0,0315	0,3464

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Baseline single cytogenetic alterations	Y	Vd Arm	93	9	9,68	84	90,32	NA	NA	NA	-	-	-	-	0,3464
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Previously Exposed to Bortezomib	N	SVd Arm	61	17	27,87	44	72,13	NA	NA	NA	3,55	1,29	9,77	0,0090	0,5711
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Previously Exposed to Bortezomib	N	Vd Arm	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,5711
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Previously Exposed to Bortezomib	Y	SVd Arm	134	25	18,66	109	81,34	NA	NA	NA	2,48	1,22	5,06	0,0095	0,5711
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neurological Toxicity	Previously Exposed to Bortezomib	Y	Vd Arm	142	11	7,75	131	92,25	NA	NA	NA	-	-	-	-	0,5711
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	total	-	SVd Arm	195	21	10,77	~~174~~	~~89,23~~	~~NA~~	~~NA~~	~~NA~~	~~1,43~~	~~0,73~~	~~2,78~~	~~0,2931~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	total	-	Vd Arm	204	15	7,35	~~189~~	~~92,65~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Gender	Female	SVd Arm	80	6	7,50	74	92,50	NA	NA	NA	1,28	0,39	4,26	0,6850	0,8499
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Gender	Female	Vd Arm	91	5	5,49	86	94,51	NA	NA	NA	-	-	-	-	0,8499
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Gender	Male	SVd Arm	115	15	13,04	100	86,96	NA	NA	NA	1,47	0,66	3,30	0,3430	0,8499
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Gender	Male	Vd Arm	113	10	8,85	103	91,15	NA	NA	NA	-	-	-	-	0,8499
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Age Group	<65	SVd Arm	86	11	12,79	75	87,21	NA	NA	NA	1,38	0,52	3,65	0,5138	0,9752
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Age Group	<65	Vd Arm	75	7	9,33	68	90,67	NA	NA	NA	-	-	-	-	0,9752
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Age Group	>=65	SVd Arm	109	10	9,17	99	90,83	NA	NA	NA	1,41	0,55	3,60	0,4696	0,9752
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Age Group	>=65	Vd Arm	129	8	6,20	121	93,80	NA	NA	NA	-	-	-	-	0,9752
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline R-ISS stage	Stage I or II	SVd Arm	173	20	11,56	153	88,44	NA	NA	NA	1,45	0,72	2,92	0,2973	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline R-ISS stage	Stage I or II	Vd Arm	174	13	7,47	161	92,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline ISS stage	Stage I or II	SVd Arm	163	20	12,27	143	87,73	NA	NA	NA	2,04	0,95	4,36	0,0605	0,0429
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline ISS stage	Stage I or II	Vd Arm	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	0,0429
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	NA	NA	NA	0,19	0,02	1,66	0,0950	0,0429
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline ISS stage	Stage III	Vd Arm	31	5	16,13	26	83,87	NA	NA	NA	-	-	-	-	0,0429
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,6045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,6045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (SAP)	Region 2	SVd Arm	61	6	9,84	55	90,16	NA	NA	NA	0,90	0,26	3,15	0,8729	0,6045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (SAP)	Region 2	Vd Arm	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,6045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (SAP)	Region 3	SVd Arm	47	4	8,51	43	91,49	NA	NA	NA	0,72	0,19	2,76	0,6322	0,6045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (SAP)	Region 3	Vd Arm	53	5	9,43	48	90,57	NA	NA	NA	-	-	-	-	0,6045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (SAP)	Region 4	SVd Arm	69	8	11,59	61	88,41	NA	NA	NA	1,67	0,54	5,13	0,3647	0,6045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (SAP)	Region 4	Vd Arm	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,6045
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	12	10,26	105	89,74	NA	NA	NA	1,30	0,56	3,05	0,5382	0,7820
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	10	7,35	126	92,65	NA	NA	NA	-	-	-	-	0,7820
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (by medical care situation)	Rest of the world	SVd Arm	78	9	11,54	69	88,46	NA	NA	NA	1,59	0,53	4,77	0,4060	0,7820
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Region (by medical care situation)	Rest of the world	Vd Arm	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,7820
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	0,47	0,09	2,50	0,3643	0,1123

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Race	Races other than White	Vd Arm	42	6	14,29	36	85,71	NA	NA	NA	-	-	-	-	0,1123
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Race	White	SVd Arm	161	19	11,80	142	88,20	NA	NA	NA	2,11	0,95	4,70	0,0625	0,1123
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Race	White	Vd Arm	162	9	5,56	153	94,44	NA	NA	NA	-	-	-	-	0,1123
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	16	9,36	155	90,64	NA	NA	NA	1,21	0,58	2,49	0,6108	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	14	7,57	171	92,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Prior PI therapies	N	SVd Arm	48	8	16,67	40	83,33	NA	NA	NA	2,79	0,73	10,60	0,1169	0,2372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Prior PI therapies	N	Vd Arm	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,2372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Prior PI therapies	Y	SVd Arm	147	13	8,84	134	91,16	NA	NA	NA	1,09	0,50	2,40	0,8231	0,2372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Prior PI therapies	Y	Vd Arm	157	12	7,64	145	92,36	NA	NA	NA	-	-	-	-	0,2372
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Prior anti-MM regimen	>1	SVd Arm	98	11	11,22	87	88,78	NA	NA	NA	1,21	0,50	2,94	0,6668	0,5915
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Prior anti-MM regimen	>1	Vd Arm	104	9	8,65	95	91,35	NA	NA	NA	-	-	-	-	0,5915
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Prior anti-MM regimen	1	SVd Arm	97	10	10,31	87	89,69	NA	NA	NA	1,76	0,63	4,86	0,2726	0,5915
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Prior anti-MM regimen	1	Vd Arm	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,5915
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline single cytogenetic alterations	N	SVd Arm	98	10	10,20	88	89,80	NA	NA	NA	1,43	0,56	3,64	0,4553	0,9139
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline single cytogenetic alterations	N	Vd Arm	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,9139
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline single cytogenetic alterations	Y	SVd Arm	97	11	11,34	86	88,66	NA	NA	NA	1,32	0,51	3,43	0,5606	0,9139

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Baseline single cytogenetic alterations	Y	Vd Arm	93	7	7,53	86	92,47	NA	NA	NA	-	-	-	-	0,9139
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Previously Exposed to Bortezomib	N	SVd Arm	61	10	16,39	51	83,61	NA	NA	NA	3,66	1,00	13,41	0,0363	0,0838
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Previously Exposed to Bortezomib	N	Vd Arm	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,0838
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Previously Exposed to Bortezomib	Y	SVd Arm	134	11	8,21	123	91,79	NA	NA	NA	0,94	0,41	2,15	0,8903	0,0838
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Hepatobiliary Disorders	Previously Exposed to Bortezomib	Y	Vd Arm	142	12	8,45	130	91,55	NA	NA	NA	-	-	-	-	0,0838
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	total	-	SVd Arm	195	21	10,77	~~174~~	~~89,23~~	~~NA~~	~~NA~~	~~NA~~	~~3,55~~	~~1,41~~	~~8,91~~	~~0,0041~~	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	total	-	Vd Arm	204	6	2,94	~~198~~	~~97,06~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Gender	Female	SVd Arm	80	8	10,00	72	90,00	NA	NA	NA	3,23	0,84	12,45	0,0736	0,5010
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Gender	Female	Vd Arm	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,5010
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Gender	Male	SVd Arm	115	13	11,30	102	88,70	NA	NA	NA	6,46	1,44	29,02	0,0053	0,5010
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Gender	Male	Vd Arm	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,5010
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Age Group	<65	SVd Arm	86	11	12,79	75	87,21	NA	36,60	NA	4,04	0,87	18,75	0,0552	0,7679
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Age Group	<65	Vd Arm	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,7679
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Age Group	>=65	SVd Arm	109	10	9,17	99	90,83	NA	NA	NA	3,02	0,93	9,78	0,0540	0,7679
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Age Group	>=65	Vd Arm	129	4	3,10	125	96,90	NA	NA	NA	-	-	-	-	0,7679
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline R-ISS stage	Stage I or II	SVd Arm	173	15	8,67	158	91,33	NA	NA	NA	2,70	0,97	7,54	0,0481	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline R-ISS stage	Stage I or II	Vd Arm	174	5	2,87	169	97,13	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline R-ISS stage	Stage III	SVd Arm	12	5	41,67	7	58,33	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline ISS stage	Stage I or II	SVd Arm	163	13	7,98	150	92,02	NA	NA	NA	2,25	0,85	5,93	0,0925	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline ISS stage	Stage I or II	Vd Arm	173	6	3,47	167	96,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline ISS stage	Stage III	SVd Arm	32	8	25,00	24	75,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,6135
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,6135
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (SAP)	Region 2	SVd Arm	61	6	9,84	55	90,16	NA	NA	NA	2,15	0,54	8,65	0,2690	0,6135
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (SAP)	Region 2	Vd Arm	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,6135
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (SAP)	Region 3	SVd Arm	47	4	8,51	43	91,49	-	-	-	-	-	-	-	0,6135
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,6135
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (SAP)	Region 4	SVd Arm	69	8	11,59	61	88,41	NA	36,60	NA	3,70	0,76	17,98	0,0824	0,6135
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (SAP)	Region 4	Vd Arm	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,6135
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	13	11,11	104	88,89	NA	NA	NA	5,11	1,41	18,48	0,0061	0,3734
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	3	2,21	133	97,79	NA	NA	NA	-	-	-	-	0,3734
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (by medical care situation)	Rest of the world	SVd Arm	78	8	10,26	70	89,74	NA	36,60	NA	2,18	0,56	8,54	0,2517	0,3734
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Region (by medical care situation)	Rest of the world	Vd Arm	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,3734
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Race	Races other than White	SVd Arm	34	4	11,76	30	88,24	NA	NA	NA	2,64	0,44	15,90	0,2725	0,6888

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Race	Races other than White	Vd Arm	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,6888
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Race	White	SVd Arm	161	17	10,56	144	89,44	NA	NA	NA	4,06	1,34	12,25	0,0074	0,6888
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Race	White	Vd Arm	162	4	2,47	158	97,53	NA	NA	NA	-	-	-	-	0,6888
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	17	9,94	154	90,06	NA	NA	NA	3,11	1,21	8,02	0,0134	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	6	3,24	179	96,76	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Prior PI therapies	N	SVd Arm	48	4	8,33	44	91,67	NA	36,60	NA	1,24	0,20	7,50	0,8171	0,2083
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Prior PI therapies	N	Vd Arm	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,2083
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Prior PI therapies	Y	SVd Arm	147	17	11,56	130	88,44	NA	NA	NA	4,80	1,60	14,37	0,0021	0,2083
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Prior PI therapies	Y	Vd Arm	157	4	2,55	153	97,45	NA	NA	NA	-	-	-	-	0,2083
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Prior anti-MM regimen	>1	SVd Arm	98	8	8,16	90	91,84	NA	NA	NA	2,10	0,62	7,14	0,2235	0,2617
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Prior anti-MM regimen	>1	Vd Arm	104	4	3,85	100	96,15	NA	NA	NA	-	-	-	-	0,2617
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Prior anti-MM regimen	1	SVd Arm	97	13	13,40	84	86,60	NA	36,60	NA	6,37	1,42	28,51	0,0055	0,2617
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,2617
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline single cytogenetic alterations	N	SVd Arm	98	12	12,24	86	87,76	NA	36,60	NA	4,17	1,15	15,13	0,0187	0,7111
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline single cytogenetic alterations	N	Vd Arm	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	0,7111
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline single cytogenetic alterations	Y	SVd Arm	97	9	9,28	88	90,72	NA	NA	NA	2,94	0,77	11,19	0,0999	0,7111

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Baseline single cytogenetic alterations	Y	Vd Arm	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,7111
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Previously Exposed to Bortezomib	N	SVd Arm	61	6	9,84	55	90,16	NA	36,60	NA	1,77	0,32	9,78	0,5084	0,3820
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,3820
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Previously Exposed to Bortezomib	Y	SVd Arm	134	15	11,19	119	88,81	NA	NA	NA	4,41	1,42	13,66	0,0052	0,3820
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Cardiac Toxicity	Previously Exposed to Bortezomib	Y	Vd Arm	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,3820
~~Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue~~	~~total~~	-	SVd Arm	~~195~~	~~104~~	~~53,33~~	~~91~~	~~46,67~~	~~5,59~~	~~3,48~~	~~13,70~~	~~2,45~~	~~1,76~~	~~3,41~~	~~0,0000~~	NA
~~Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue~~	~~total~~	-	Vd Arm	~~204~~	~~55~~	~~26,96~~	~~149~~	~~73,04~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Gender	Female	SVd Arm	80	46	57,50	34	42,50	4,86	2,33	24,15	3,92	2,19	7,02	0,0000	0,0396
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Gender	Female	Vd Arm	91	18	19,78	73	80,22	NA	NA	NA	-	-	-	-	0,0396
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Gender	Male	SVd Arm	115	58	50,43	57	49,57	7,33	3,48	NA	1,85	1,22	2,80	0,0035	0,0396
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Gender	Male	Vd Arm	113	37	32,74	76	67,26	NA	12,88	NA	-	-	-	-	0,0396
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Age Group	<65	SVd Arm	86	47	54,65	39	45,35	5,59	2,99	NA	2,53	1,46	4,39	0,0007	0,9898
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Age Group	<65	Vd Arm	75	20	26,67	55	73,33	NA	NA	NA	-	-	-	-	0,9898
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Age Group	>=65	SVd Arm	109	57	52,29	52	47,71	5,82	2,33	NA	2,52	1,64	3,86	0,0000	0,9898
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Age Group	>=65	Vd Arm	129	35	27,13	94	72,87	NA	NA	NA	-	-	-	-	0,9898
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline R-ISS stage	Stage I or II	SVd Arm	173	91	52,60	82	47,40	6,70	3,68	24,15	2,46	1,72	3,51	0,0000	0,6068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline R-ISS stage	Stage I or II	Vd Arm	174	46	26,44	128	73,56	NA	NA	NA	-	-	-	-	0,6068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline R-ISS stage	Stage III	SVd Arm	12	6	50,00	6	50,00	1,41	0,69	NA	3,65	0,85	15,66	0,0683	0,6068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline R-ISS stage	Stage III	Vd Arm	16	5	31,25	11	68,75	NA	8,61	NA	-	-	-	-	0,6068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline ISS stage	Stage I or II	SVd Arm	163	87	53,37	76	46,63	5,82	3,48	24,15	2,47	1,73	3,52	0,0000	0,8970
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline ISS stage	Stage I or II	Vd Arm	173	47	27,17	126	72,83	NA	NA	NA	-	-	-	-	0,8970

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline ISS stage	Stage III	SVd Arm	32	17	53,12	15	46,88	5,59	1,41	NA	2,62	1,11	6,16	0,0221	0,8970
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline ISS stage	Stage III	Vd Arm	31	8	25,81	23	74,19	NA	12,88	NA	-	-	-	-	0,8970
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (SAP)	Region 1	SVd Arm	18	11	61,11	7	38,89	0,95	0,26	NA	4,10	1,11	15,14	0,0225	0,4068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (SAP)	Region 1	Vd Arm	17	5	29,41	12	70,59	NA	3,06	NA	-	-	-	-	0,4068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (SAP)	Region 2	SVd Arm	61	39	63,93	22	36,07	1,41	0,59	5,59	1,86	1,14	3,05	0,0123	0,4068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (SAP)	Region 2	Vd Arm	64	28	43,75	36	56,25	7,66	5,68	NA	-	-	-	-	0,4068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (SAP)	Region 3	SVd Arm	47	19	40,43	28	59,57	13,70	10,55	NA	2,43	1,05	5,62	0,0315	0,4068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (SAP)	Region 3	Vd Arm	53	8	15,09	45	84,91	NA	NA	NA	-	-	-	-	0,4068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (SAP)	Region 4	SVd Arm	69	35	50,72	34	49,28	7,33	3,98	NA	3,44	1,83	6,45	0,0000	0,4068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (SAP)	Region 4	Vd Arm	70	14	20,00	56	80,00	NA	NA	NA	-	-	-	-	0,4068
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	61	52,14	56	47,86	6,47	2,60	NA	2,07	1,38	3,12	0,0004	0,2426
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	38	27,94	98	72,06	NA	NA	NA	-	-	-	-	0,2426
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (by medical care situation)	Rest of the world	SVd Arm	78	43	55,13	35	44,87	5,32	2,33	NA	3,16	1,77	5,63	0,0000	0,2426
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Region (by medical care situation)	Rest of the world	Vd Arm	68	17	25,00	51	75,00	NA	NA	NA	-	-	-	-	0,2426
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Race	Races other than White	SVd Arm	34	19	55,88	15	44,12	4,07	1,22	NA	1,99	0,96	4,11	0,0590	0,5442
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Race	Races other than White	Vd Arm	42	15	35,71	27	64,29	NA	7,66	NA	-	-	-	-	0,5442
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Race	White	SVd Arm	161	85	52,80	76	47,20	6,70	3,58	24,15	2,56	1,75	3,75	0,0000	0,5442
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Race	White	Vd Arm	162	40	24,69	122	75,31	NA	NA	NA	-	-	-	-	0,5442
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	5	83,33	1	16,67	0,67	0,10	NA	3,93	0,42	36,69	0,1983	0,6566
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	3	60,00	2	40,00	3,75	2,37	NA	-	-	-	-	0,6566
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	88	51,46	83	48,54	6,77	3,98	24,15	2,36	1,65	3,36	0,0000	0,6566
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	49	26,49	136	73,51	NA	NA	NA	-	-	-	-	0,6566

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Prior PI therapies	N	SVd Arm	48	23	47,92	25	52,08	8,87	3,48	NA	2,05	1,03	4,10	0,0378	0,5724
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Prior PI therapies	N	Vd Arm	47	13	27,66	34	72,34	NA	NA	NA	-	-	-	-	0,5724
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Prior PI therapies	Y	SVd Arm	147	81	55,10	66	44,90	4,86	2,33	11,53	2,58	1,77	3,75	0,0000	0,5724
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Prior PI therapies	Y	Vd Arm	157	42	26,75	115	73,25	NA	NA	NA	-	-	-	-	0,5724
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Prior anti-MM regimen	>1	SVd Arm	98	50	51,02	48	48,98	6,70	4,86	NA	1,98	1,26	3,11	0,0026	0,1906
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Prior anti-MM regimen	>1	Vd Arm	104	31	29,81	73	70,19	NA	12,88	NA	-	-	-	-	0,1906
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Prior anti-MM regimen	1	SVd Arm	97	54	55,67	43	44,33	3,68	1,64	NA	3,08	1,90	5,01	0,0000	0,1906
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Prior anti-MM regimen	1	Vd Arm	100	24	24,00	76	76,00	NA	NA	NA	-	-	-	-	0,1906
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline single cytogenetic alterations	N	SVd Arm	98	49	50,00	49	50,00	7,33	4,86	NA	2,11	1,34	3,34	0,0011	0,5831
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline single cytogenetic alterations	N	Vd Arm	111	31	27,93	80	72,07	NA	NA	NA	-	-	-	-	0,5831
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline single cytogenetic alterations	Y	SVd Arm	97	55	56,70	42	43,30	3,98	1,64	13,70	2,55	1,57	4,14	0,0001	0,5831
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Baseline single cytogenetic alterations	Y	Vd Arm	93	24	25,81	69	74,19	NA	NA	NA	-	-	-	-	0,5831
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Previously Exposed to Bortezomib	N	SVd Arm	61	31	50,82	30	49,18	8,87	3,48	NA	2,68	1,40	5,11	0,0020	0,8056
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Previously Exposed to Bortezomib	N	Vd Arm	62	14	22,58	48	77,42	NA	NA	NA	-	-	-	-	0,8056
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Previously Exposed to Bortezomib	Y	SVd Arm	134	73	54,48	61	45,52	4,57	2,33	11,53	2,43	1,65	3,58	0,0000	0,8056
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Fatigue	Previously Exposed to Bortezomib	Y	Vd Arm	142	41	28,87	101	71,13	NA	NA	NA	-	-	-	-	0,8056
~~Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages~~	~~total~~	-	SVd Arm	~~195~~	~~34~~	~~17,44~~	~~161~~	~~82,56~~	~~NA~~	~~32,43~~	~~NA~~	~~3,00~~	~~1,57~~	~~5,74~~	~~0,0005~~	NA
~~Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages~~	~~total~~	-	Vd Arm	~~204~~	~~13~~	~~6,37~~	~~191~~	~~93,63~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Gender	Female	SVd Arm	80	12	15,00	68	85,00	NA	NA	NA	1,90	0,70	5,12	0,1990	0,2935
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Gender	Female	Vd Arm	91	8	8,79	83	91,21	NA	NA	NA	-	-	-	-	0,2935
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Gender	Male	SVd Arm	115	22	19,13	93	80,87	NA	32,43	NA	4,00	1,51	10,62	0,0026	0,2935

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Gender	Male	Vd Arm	113	5	4,42	108	95,58	NA	NA	NA	-	-	-	-	0,2935
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Age Group	<65	SVd Arm	86	17	19,77	69	80,23	NA	32,43	NA	4,02	1,31	12,31	0,0092	0,5660
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Age Group	<65	Vd Arm	75	4	5,33	71	94,67	NA	NA	NA	-	-	-	-	0,5660
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Age Group	>=65	SVd Arm	109	17	15,60	92	84,40	NA	29,31	NA	2,66	1,14	6,22	0,0189	0,5660
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Age Group	>=65	Vd Arm	129	9	6,98	120	93,02	NA	NA	NA	-	-	-	-	0,5660
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline R-ISS stage	Stage I or II	SVd Arm	173	30	17,34	143	82,66	NA	NA	NA	2,96	1,44	6,06	0,0019	0,5108
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline R-ISS stage	Stage I or II	Vd Arm	174	10	5,75	164	94,25	NA	NA	NA	-	-	-	-	0,5108
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline R-ISS stage	Stage III	SVd Arm	12	3	25,00	9	75,00	32,43	NA	NA	1,47	0,21	10,33	0,6950	0,5108
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline R-ISS stage	Stage III	Vd Arm	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,5108
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline ISS stage	Stage I or II	SVd Arm	163	29	17,79	134	82,21	NA	NA	NA	3,03	1,48	6,23	0,0015	0,4025
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline ISS stage	Stage I or II	Vd Arm	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	0,4025
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline ISS stage	Stage III	SVd Arm	32	5	15,62	27	84,38	32,43	32,43	NA	1,48	0,32	6,75	0,6101	0,4025
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline ISS stage	Stage III	Vd Arm	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,4025
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (SAP)	Region 1	SVd Arm	18	2	11,11	16	88,89	-	-	-	-	-	-	-	0,1827
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	-	-	-	-	-	-	-	0,1827
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (SAP)	Region 2	SVd Arm	61	13	21,31	48	78,69	29,31	21,91	NA	1,72	0,67	4,39	0,2518	0,1827
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (SAP)	Region 2	Vd Arm	64	7	10,94	57	89,06	NA	NA	NA	-	-	-	-	0,1827
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (SAP)	Region 3	SVd Arm	47	5	10,64	42	89,36	NA	NA	NA	2,24	0,42	12,09	0,3356	0,1827

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (SAP)	Region 3	Vd Arm	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,1827
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (SAP)	Region 4	SVd Arm	69	14	20,29	55	79,71	NA	32,43	NA	8,97	2,00	40,16	0,0006	0,1827
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (SAP)	Region 4	Vd Arm	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,1827
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	15	12,82	102	87,18	NA	NA	NA	1,53	0,69	3,37	0,2900	0,0256
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	11	8,09	125	91,91	NA	NA	NA	-	-	-	-	0,0256
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (by medical care situation)	Rest of the world	SVd Arm	78	19	24,36	59	75,64	NA	32,43	NA	10,24	2,35	44,51	0,0001	0,0256
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Region (by medical care situation)	Rest of the world	Vd Arm	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,0256
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Race	Races other than White	SVd Arm	34	6	17,65	28	82,35	32,43	32,43	NA	2,80	0,53	14,73	0,2061	0,9360
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Race	Races other than White	Vd Arm	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,9360
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Race	White	SVd Arm	161	28	17,39	133	82,61	NA	NA	NA	2,60	1,28	5,29	0,0065	0,9360
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Race	White	Vd Arm	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	0,9360
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	31	18,13	140	81,87	NA	32,43	NA	3,38	1,68	6,79	0,0003	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	12	6,49	173	93,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Prior PI therapies	N	SVd Arm	48	10	20,83	38	79,17	NA	NA	NA	12,47	1,54	101,02	0,0033	0,1307
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,1307
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Prior PI therapies	Y	SVd Arm	147	24	16,33	123	83,67	NA	29,31	NA	2,28	1,13	4,58	0,0180	0,1307

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Prior PI therapies	Y	Vd Arm	157	12	7,64	145	92,36	NA	NA	NA	-	-	-	-	0,1307
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Prior anti-MM regimen	>1	SVd Arm	98	14	14,29	84	85,71	NA	NA	NA	2,39	0,96	5,98	0,0552	0,5059
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Prior anti-MM regimen	>1	Vd Arm	104	7	6,73	97	93,27	NA	NA	NA	-	-	-	-	0,5059
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Prior anti-MM regimen	1	SVd Arm	97	20	20,62	77	79,38	NA	32,43	NA	3,72	1,47	9,40	0,0031	0,5059
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Prior anti-MM regimen	1	Vd Arm	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,5059
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline single cytogenetic alterations	N	SVd Arm	98	20	20,41	78	79,59	NA	32,43	NA	3,18	1,38	7,35	0,0045	0,7037
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline single cytogenetic alterations	N	Vd Arm	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,7037
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline single cytogenetic alterations	Y	SVd Arm	97	14	14,43	83	85,57	NA	29,31	NA	2,46	0,88	6,87	0,0767	0,7037
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Baseline single cytogenetic alterations	Y	Vd Arm	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,7037
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Previously Exposed to Bortezomib	N	SVd Arm	61	12	19,67	49	80,33	NA	NA	NA	14,22	1,78	113,54	0,0014	0,0952
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,0952
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Previously Exposed to Bortezomib	Y	SVd Arm	134	22	16,42	112	83,58	NA	29,31	NA	2,19	1,07	4,49	0,0290	0,0952
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Haemorrhages	Previously Exposed to Bortezomib	Y	Vd Arm	142	12	8,45	130	91,55	NA	NA	NA	-	-	-	-	0,0952
~~Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral~~	~~total~~	-	SVd Arm	~~195~~	~~65~~	~~33,33~~	~~130~~	~~66,67~~	~~25,33~~	~~13,83~~	~~NA~~	~~0,61~~	~~0,44~~	~~0,84~~	~~0,0024~~	NA
~~Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral~~	~~total~~	-	Vd Arm	~~204~~	~~95~~	~~46,57~~	~~109~~	~~53,43~~	~~13,11~~	~~4,86~~	~~19,15~~	-	-	-	-	NA
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Gender	Female	SVd Arm	80	28	35,00	52	65,00	25,33	8,08	NA	0,60	0,36	0,99	0,0420	0,9797
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Gender	Female	Vd Arm	91	42	46,15	49	53,85	7,56	4,86	NA	-	-	-	-	0,9797
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Gender	Male	SVd Arm	115	37	32,17	78	67,83	25,79	14,55	NA	0,60	0,39	0,93	0,0193	0,9797

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Gender	Male	Vd Arm	113	53	46,90	60	53,10	14,36	4,37	NA	-	-	-	-	0,9797
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Age Group	<65	SVd Arm	86	30	34,88	56	65,12	25,33	8,77	NA	0,54	0,33	0,89	0,0153	0,6104
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Age Group	<65	Vd Arm	75	37	49,33	38	50,67	7,20	4,17	NA	-	-	-	-	0,6104
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Age Group	>=65	SVd Arm	109	35	32,11	74	67,89	37,98	18,53	NA	0,64	0,42	0,99	0,0426	0,6104
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Age Group	>=65	Vd Arm	129	58	44,96	71	55,04	14,36	4,86	NA	-	-	-	-	0,6104
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline R-ISS stage	Stage I or II	SVd Arm	173	60	34,68	113	65,32	25,33	13,83	NA	0,63	0,45	0,88	0,0060	0,7659
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline R-ISS stage	Stage I or II	Vd Arm	174	82	47,13	92	52,87	13,11	4,86	20,96	-	-	-	-	0,7659
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline R-ISS stage	Stage III	SVd Arm	12	3	25,00	9	75,00	25,79	7,10	NA	0,47	0,07	2,98	0,4171	0,7659
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline R-ISS stage	Stage III	Vd Arm	16	4	25,00	12	75,00	NA	7,56	NA	-	-	-	-	0,7659
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline ISS stage	Stage I or II	SVd Arm	163	58	35,58	105	64,42	25,33	9,95	NA	0,61	0,44	0,86	0,0045	0,9676
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline ISS stage	Stage I or II	Vd Arm	173	83	47,98	90	52,02	8,97	4,86	19,15	-	-	-	-	0,9676
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline ISS stage	Stage III	SVd Arm	32	7	21,88	25	78,12	NA	25,79	NA	0,63	0,24	1,62	0,3302	0,9676
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline ISS stage	Stage III	Vd Arm	31	12	38,71	19	61,29	13,11	4,37	NA	-	-	-	-	0,9676
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (SAP)	Region 1	SVd Arm	18	2	11,11	16	88,89	NA	9,95	NA	0,22	0,04	1,09	0,0435	0,3581
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (SAP)	Region 1	Vd Arm	17	8	47,06	9	52,94	6,77	1,41	NA	-	-	-	-	0,3581
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (SAP)	Region 2	SVd Arm	61	22	36,07	39	63,93	14,55	6,87	NA	0,64	0,37	1,11	0,1093	0,3581
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (SAP)	Region 2	Vd Arm	64	32	50,00	32	50,00	4,14	2,76	NA	-	-	-	-	0,3581
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (SAP)	Region 3	SVd Arm	47	21	44,68	26	55,32	18,53	7,16	NA	0,91	0,49	1,72	0,7786	0,3581

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (SAP)	Region 3	Vd Arm	53	22	41,51	31	58,49	13,11	4,86	NA	-	-	-	-	0,3581
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (SAP)	Region 4	SVd Arm	69	20	28,99	49	71,01	25,79	13,83	NA	0,55	0,31	0,97	0,0349	0,3581
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (SAP)	Region 4	Vd Arm	70	33	47,14	37	52,86	14,52	5,78	NA	-	-	-	-	0,3581
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	41	35,04	76	64,96	18,53	8,77	NA	0,66	0,44	0,99	0,0432	0,5292
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	59	43,38	77	56,62	13,11	4,86	NA	-	-	-	-	0,5292
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (by medical care situation)	Rest of the world	SVd Arm	78	24	30,77	54	69,23	25,79	13,83	NA	0,53	0,31	0,90	0,0171	0,5292
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Region (by medical care situation)	Rest of the world	Vd Arm	68	36	52,94	32	47,06	14,36	4,37	NA	-	-	-	-	0,5292
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Race	Races other than White	SVd Arm	34	11	32,35	23	67,65	25,79	7,10	NA	0,38	0,16	0,87	0,0180	0,2224
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Race	Races other than White	Vd Arm	42	26	61,90	16	38,10	4,37	2,89	21,75	-	-	-	-	0,2224
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Race	White	SVd Arm	161	54	33,54	107	66,46	25,33	13,83	NA	0,66	0,46	0,96	0,0266	0,2224
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Race	White	Vd Arm	162	69	42,59	93	57,41	13,11	6,01	NA	-	-	-	-	0,2224
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	3	50,00	3	50,00	7,98	5,55	NA	0,64	0,09	4,62	0,6540	0,9724
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	2	40,00	3	60,00	NA	4,14	NA	-	-	-	-	0,9724
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	55	32,16	116	67,84	25,79	13,83	NA	0,62	0,44	0,87	0,0055	0,9724
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	85	45,95	100	54,05	13,11	5,78	19,15	-	-	-	-	0,9724
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Prior PI therapies	N	SVd Arm	48	15	31,25	33	68,75	37,98	8,77	NA	0,40	0,21	0,79	0,0062	0,1631
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Prior PI therapies	N	Vd Arm	47	24	51,06	23	48,94	4,86	2,79	NA	-	-	-	-	0,1631
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Prior PI therapies	Y	SVd Arm	147	50	34,01	97	65,99	25,33	13,83	NA	0,69	0,48	1,00	0,0492	0,1631

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Prior PI therapies	Y	Vd Arm	157	71	45,22	86	54,78	13,11	6,01	21,75	-	-	-	-	0,1631
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Prior anti-MM regimen	>1	SVd Arm	98	27	27,55	71	72,45	37,98	13,83	NA	0,52	0,32	0,85	0,0076	0,3781
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Prior anti-MM regimen	>1	Vd Arm	104	44	42,31	60	57,69	13,11	5,78	NA	-	-	-	-	0,3781
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Prior anti-MM regimen	1	SVd Arm	97	38	39,18	59	60,82	18,53	8,54	NA	0,69	0,45	1,06	0,0891	0,3781
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Prior anti-MM regimen	1	Vd Arm	100	51	51,00	49	49,00	7,20	3,48	20,96	-	-	-	-	0,3781
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline single cytogenetic alterations	N	SVd Arm	98	29	29,59	69	70,41	37,98	25,33	NA	0,48	0,30	0,77	0,0018	0,1130
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline single cytogenetic alterations	N	Vd Arm	111	55	49,55	56	50,45	8,97	4,14	21,75	-	-	-	-	0,1130
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline single cytogenetic alterations	Y	SVd Arm	97	36	37,11	61	62,89	13,83	8,08	NA	0,82	0,52	1,30	0,3971	0,1130
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Baseline single cytogenetic alterations	Y	Vd Arm	93	40	43,01	53	56,99	14,36	6,01	NA	-	-	-	-	0,1130
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Previously Exposed to Bortezomib	N	SVd Arm	61	23	37,70	38	62,30	37,98	7,43	NA	0,51	0,29	0,93	0,0245	0,5993
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Previously Exposed to Bortezomib	N	Vd Arm	62	31	50,00	31	50,00	4,86	3,02	NA	-	-	-	-	0,5993
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Previously Exposed to Bortezomib	Y	SVd Arm	134	42	31,34	92	68,66	25,33	13,83	NA	0,62	0,42	0,92	0,0167	0,5993
Patients with at least one non-severe AESI or AECI (CTCAE v4,03 grade 1 or 2) Neuropathy Peripheral	Previously Exposed to Bortezomib	Y	Vd Arm	142	64	45,07	78	54,93	13,11	6,05	21,75	-	-	-	-	0,5993
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	total	-	SVd Arm	195	80	41,03	115	58,97	30,16	15,44	NA	2,60	1,75	3,86	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	total	-	Vd Arm	204	36	17,65	168	82,35	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Gender	Female	SVd Arm	80	33	41,25	47	58,75	24,48	15,44	NA	3,18	1,62	6,24	0,0004	0,6736
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Gender	Female	Vd Arm	91	16	17,58	75	82,42	NA	NA	NA	-	-	-	-	0,6736
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Gender	Male	SVd Arm	115	47	40,87	68	59,13	NA	9,79	NA	2,64	1,56	4,48	0,0002	0,6736
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Gender	Male	Vd Arm	113	20	17,70	93	82,30	NA	NA	NA	-	-	-	-	0,6736

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Age Group	<65	SVd Arm	86	35	40,70	51	59,30	30,16	9,92	NA	2,13	1,16	3,90	0,0127	0,4068
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Age Group	<65	Vd Arm	75	16	21,33	59	78,67	NA	NA	NA	-	-	-	-	0,4068
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Age Group	>=65	SVd Arm	109	45	41,28	64	58,72	NA	4,17	NA	2,99	1,76	5,09	0,0000	0,4068
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Age Group	>=65	Vd Arm	129	20	15,50	109	84,50	NA	NA	NA	-	-	-	-	0,4068
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	73	42,20	100	57,80	24,48	15,44	NA	2,81	1,82	4,33	0,0000	0,1189
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	29	16,67	145	83,33	NA	NA	NA	-	-	-	-	0,1189
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline R-ISS stage	Stage III	SVd Arm	12	4	33,33	8	66,67	NA	2,10	NA	0,89	0,22	3,53	0,8646	0,1189
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline R-ISS stage	Stage III	Vd Arm	16	6	37,50	10	62,50	NA	2,37	NA	-	-	-	-	0,1189
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline ISS stage	Stage I or II	SVd Arm	163	70	42,94	93	57,06	24,48	9,92	NA	3,02	1,93	4,72	0,0000	0,0569
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline ISS stage	Stage I or II	Vd Arm	173	27	15,61	146	84,39	NA	NA	NA	-	-	-	-	0,0569
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline ISS stage	Stage III	SVd Arm	32	10	31,25	22	68,75	NA	NA	NA	1,13	0,45	2,80	0,7929	0,0569
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline ISS stage	Stage III	Vd Arm	31	9	29,03	22	70,97	NA	10,97	NA	-	-	-	-	0,0569
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (SAP)	Region 1	SVd Arm	18	8	44,44	10	55,56	9,79	0,95	NA	2,20	0,41	11,66	0,3441	0,7985
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (SAP)	Region 1	Vd Arm	17	5	29,41	12	70,59	NA	10,12	NA	-	-	-	-	0,7985
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (SAP)	Region 2	SVd Arm	61	31	50,82	30	49,18	4,17	1,87	NA	2,36	1,27	4,41	0,0054	0,7985
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (SAP)	Region 2	Vd Arm	64	15	23,44	49	76,56	NA	NA	NA	-	-	-	-	0,7985
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (SAP)	Region 3	SVd Arm	47	17	36,17	30	63,83	NA	16,33	NA	4,23	1,54	11,58	0,0024	0,7985
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (SAP)	Region 3	Vd Arm	53	5	9,43	48	90,57	NA	NA	NA	-	-	-	-	0,7985
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (SAP)	Region 4	SVd Arm	69	24	34,78	45	65,22	30,16	24,48	NA	2,55	1,24	5,27	0,0086	0,7985
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (SAP)	Region 4	Vd Arm	70	11	15,71	59	84,29	NA	NA	NA	-	-	-	-	0,7985
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	47	40,17	70	59,83	NA	9,92	NA	2,27	1,40	3,69	0,0006	0,3490
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	26	19,12	110	80,88	NA	NA	NA	-	-	-	-	0,3490

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (by medical care situation)	Rest of the world	SVd Arm	78	33	42,31	45	57,69	30,16	6,51	NA	3,43	1,68	7,02	0,0003	0,3490
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Region (by medical care situation)	Rest of the world	Vd Arm	68	10	14,71	58	85,29	NA	NA	NA	-	-	-	-	0,3490
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Race	Races other than White	SVd Arm	34	8	23,53	26	76,47	NA	NA	NA	1,53	0,51	4,56	0,4475	0,3730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Race	Races other than White	Vd Arm	42	6	14,29	36	85,71	NA	NA	NA	-	-	-	-	0,3730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Race	White	SVd Arm	161	72	44,72	89	55,28	18,63	9,79	NA	2,60	1,69	4,00	0,0000	0,3730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Race	White	Vd Arm	162	30	18,52	132	81,48	NA	NA	NA	-	-	-	-	0,3730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	67	39,18	104	60,82	30,16	16,33	NA	2,35	1,55	3,56	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	34	18,38	151	81,62	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Prior PI therapies	N	SVd Arm	48	18	37,50	30	62,50	30,16	24,48	NA	2,55	1,05	6,18	0,0330	0,9602
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Prior PI therapies	N	Vd Arm	47	7	14,89	40	85,11	NA	NA	NA	-	-	-	-	0,9602
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Prior PI therapies	Y	SVd Arm	147	62	42,18	85	57,82	18,63	9,79	NA	2,61	1,68	4,06	0,0000	0,9602
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Prior PI therapies	Y	Vd Arm	157	29	18,47	128	81,53	NA	NA	NA	-	-	-	-	0,9602
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Prior anti-MM regimen	>1	SVd Arm	98	40	40,82	58	59,18	16,33	6,51	NA	2,85	1,61	5,04	0,0002	0,6556
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Prior anti-MM regimen	>1	Vd Arm	104	17	16,35	87	83,65	NA	NA	NA	-	-	-	-	0,6556
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Prior anti-MM regimen	1	SVd Arm	97	40	41,24	57	58,76	30,16	9,92	NA	2,38	1,37	4,13	0,0015	0,6556
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Prior anti-MM regimen	1	Vd Arm	100	19	19,00	81	81,00	NA	NA	NA	-	-	-	-	0,6556
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline single cytogenetic alterations	N	SVd Arm	98	31	31,63	67	68,37	NA	30,16	NA	1,98	1,09	3,59	0,0220	0,3387
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline single cytogenetic alterations	N	Vd Arm	111	18	16,22	93	83,78	NA	NA	NA	-	-	-	-	0,3387
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline single cytogenetic alterations	Y	SVd Arm	97	49	50,52	48	49,48	9,92	4,17	NA	2,94	1,69	5,13	0,0001	0,3387
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Baseline single cytogenetic alterations	Y	Vd Arm	93	18	19,35	75	80,65	NA	NA	NA	-	-	-	-	0,3387

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Previously Exposed to Bortezomib	N	SVd Arm	61	21	34,43	40	65,57	30,16	24,48	NA	2,41	1,09	5,32	0,0255	0,7570
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Previously Exposed to Bortezomib	N	Vd Arm	62	9	14,52	53	85,48	NA	NA	NA	-	-	-	-	0,7570
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Previously Exposed to Bortezomib	Y	SVd Arm	134	59	44,03	75	55,97	16,33	5,09	NA	2,78	1,75	4,41	0,0000	0,7570
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Thrombocytopenia	Previously Exposed to Bortezomib	Y	Vd Arm	142	27	19,01	115	80,99	NA	NA	NA	-	-	-	-	0,7570
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	total	-	SVd Arm	195	20	10,26	175	89,74	NA	44,52	NA	2,61	1,14	5,97	0,0187	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	total	-	Vd Arm	204	8	3,92	196	96,08	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Gender	Female	SVd Arm	80	9	11,25	71	88,75	NA	NA	NA	2,00	0,66	6,08	0,2126	0,6180
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Gender	Female	Vd Arm	91	5	5,49	86	94,51	NA	NA	NA	-	-	-	-	0,6180
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Gender	Male	SVd Arm	115	11	9,57	104	90,43	NA	44,52	NA	3,09	0,85	11,31	0,0727	0,6180
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Gender	Male	Vd Arm	113	3	2,65	110	97,35	NA	NA	NA	-	-	-	-	0,6180
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Age Group	<65	SVd Arm	86	10	11,63	76	88,37	NA	NA	NA	9,68	1,19	79,00	0,0116	0,1216
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Age Group	<65	Vd Arm	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,1216
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Age Group	>=65	SVd Arm	109	10	9,17	99	90,83	NA	44,52	NA	1,54	0,57	4,18	0,3887	0,1216
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Age Group	>=65	Vd Arm	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	0,1216
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	17	9,83	156	90,17	NA	44,52	NA	2,75	1,07	7,03	0,0279	0,9560
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	6	3,45	168	96,55	NA	NA	NA	-	-	-	-	0,9560
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline R-ISS stage	Stage III	SVd Arm	12	2	16,67	10	83,33	NA	NA	NA	2,58	0,36	18,48	0,3268	0,9560
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline R-ISS stage	Stage III	Vd Arm	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,9560
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline ISS stage	Stage I or II	SVd Arm	163	17	10,43	146	89,57	NA	44,52	NA	2,86	1,12	7,30	0,0218	0,7126
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline ISS stage	Stage I or II	Vd Arm	173	6	3,47	167	96,53	NA	NA	NA	-	-	-	-	0,7126
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline ISS stage	Stage III	SVd Arm	32	3	9,38	29	90,62	NA	NA	NA	1,95	0,32	11,80	0,4589	0,7126
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline ISS stage	Stage III	Vd Arm	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,7126

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,3325
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,3325
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (SAP)	Region 2	SVd Arm	61	6	9,84	55	90,16	44,52	27,07	NA	1,59	0,41	6,15	0,4990	0,3325
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (SAP)	Region 2	Vd Arm	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,3325
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (SAP)	Region 3	SVd Arm	47	3	6,38	44	93,62	NA	NA	NA	1,49	0,25	9,10	0,6608	0,3325
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (SAP)	Region 3	Vd Arm	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,3325
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (SAP)	Region 4	SVd Arm	69	10	14,49	59	85,51	NA	NA	NA	6,42	1,39	29,59	0,0065	0,3325
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (SAP)	Region 4	Vd Arm	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,3325
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	11	9,40	106	90,60	NA	44,52	NA	2,07	0,75	5,71	0,1517	0,3416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	6	4,41	130	95,59	NA	NA	NA	-	-	-	-	0,3416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (by medical care situation)	Rest of the world	SVd Arm	78	9	11,54	69	88,46	NA	NA	NA	5,07	1,08	23,79	0,0227	0,3416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Region (by medical care situation)	Rest of the world	Vd Arm	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,3416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Race	Races other than White	SVd Arm	34	1	2,94	33	97,06	NA	NA	NA	1,20	0,07	19,44	0,8969	0,6008
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,6008
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Race	White	SVd Arm	161	19	11,80	142	88,20	NA	44,52	NA	2,62	1,09	6,30	0,0256	0,6008
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Race	White	Vd Arm	162	7	4,32	155	95,68	NA	NA	NA	-	-	-	-	0,6008
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	19	11,11	152	88,89	NA	44,52	NA	2,52	1,09	5,83	0,0249	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	8	4,32	177	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Prior PI therapies	N	SVd Arm	48	2	4,17	46	95,83	NA	NA	NA	1,91	0,17	21,08	0,5914	0,7883
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,7883

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Prior PI therapies	Y	SVd Arm	147	18	12,24	129	87,76	NA	44,52	NA	2,71	1,12	6,55	0,0212	0,7883
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Prior PI therapies	Y	Vd Arm	157	7	4,46	150	95,54	NA	NA	NA	-	-	-	-	0,7883
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Prior anti-MM regimen	>1	SVd Arm	98	12	12,24	86	87,76	44,52	NA	NA	3,12	0,99	9,85	0,0407	0,6417
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Prior anti-MM regimen	>1	Vd Arm	104	4	3,85	100	96,15	NA	NA	NA	-	-	-	-	0,6417
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Prior anti-MM regimen	1	SVd Arm	97	8	8,25	89	91,75	NA	NA	NA	2,10	0,63	7,00	0,2148	0,6417
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Prior anti-MM regimen	1	Vd Arm	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,6417
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline single cytogenetic alterations	N	SVd Arm	98	7	7,14	91	92,86	44,52	44,52	NA	2,65	0,65	10,79	0,1592	0,9723
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline single cytogenetic alterations	N	Vd Arm	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	0,9723
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline single cytogenetic alterations	Y	SVd Arm	97	13	13,40	84	86,60	NA	NA	NA	2,57	0,91	7,22	0,0642	0,9723
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Baseline single cytogenetic alterations	Y	Vd Arm	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,9723
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Previously Exposed to Bortezomib	N	SVd Arm	61	3	4,92	58	95,08	NA	NA	NA	3,04	0,32	29,32	0,3117	0,9105
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,9105
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Previously Exposed to Bortezomib	Y	SVd Arm	134	17	12,69	117	87,31	NA	44,52	NA	2,64	1,08	6,48	0,0272	0,9105
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neutropenia	Previously Exposed to Bortezomib	Y	Vd Arm	142	7	4,93	135	95,07	NA	NA	NA	-	-	-	-	0,9105
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	total	-	SVd Arm	195	15	7,69	180	92,31	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	total	-	Vd Arm	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Gender	Female	SVd Arm	80	8	10,00	72	90,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Gender	Male	SVd Arm	115	7	6,09	108	93,91	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Age Group	<65	SVd Arm	86	2	2,33	84	97,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Age Group	>=65	SVd Arm	109	13	11,93	96	88,07	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline R-ISS stage	Stage I or II	SVd Arm	173	13	7,51	160	92,49	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline ISS stage	Stage I or II	SVd Arm	163	13	7,98	150	92,02	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (SAP)	Region 2	SVd Arm	61	6	9,84	55	90,16	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (SAP)	Region 3	SVd Arm	47	2	4,26	45	95,74	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (SAP)	Region 4	SVd Arm	69	4	5,80	65	94,20	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	9	7,69	108	92,31	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (by medical care situation)	Rest of the world	SVd Arm	78	6	7,69	72	92,31	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Race	Races other than White	SVd Arm	34	3	8,82	31	91,18	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Race	White	SVd Arm	161	12	7,45	149	92,55	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	13	7,60	158	92,40	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Prior PI therapies	N	SVd Arm	48	4	8,33	44	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Prior PI therapies	Y	SVd Arm	147	11	7,48	136	92,52	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Prior anti-MM regimen	>1	SVd Arm	98	9	9,18	89	90,82	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Prior anti-MM regimen	1	SVd Arm	97	6	6,19	91	93,81	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline single cytogenetic alterations	N	SVd Arm	98	8	8,16	90	91,84	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline single cytogenetic alterations	Y	SVd Arm	97	7	7,22	90	92,78	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Previously Exposed to Bortezomib	N	SVd Arm	61	5	8,20	56	91,80	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Previously Exposed to Bortezomib	Y	SVd Arm	134	10	7,46	124	92,54	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Nausea	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	total	-	SVd Arm	195	8	4,10	187	95,90	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	total	-	Vd Arm	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Gender	Female	SVd Arm	80	5	6,25	75	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Gender	Male	SVd Arm	115	3	2,61	112	97,39	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Age Group	<65	SVd Arm	86	5	5,81	81	94,19	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline R-ISS stage	Stage I or II	SVd Arm	173	7	4,05	166	95,95	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline ISS stage	Stage I or II	SVd Arm	163	8	4,91	155	95,09	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (SAP)	Region 1	SVd Arm	18	2	11,11	16	88,89	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (SAP)	Region 2	SVd Arm	61	3	4,92	58	95,08	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (SAP)	Region 4	SVd Arm	69	3	4,35	66	95,65	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (by medical care situation)	Rest of the world	SVd Arm	78	4	5,13	74	94,87	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Race	Races other than White	SVd Arm	34	5	14,71	29	85,29	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Race	White	SVd Arm	161	3	1,86	158	98,14	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	6	3,51	165	96,49	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Prior PI therapies	N	SVd Arm	48	4	8,33	44	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Prior PI therapies	Y	SVd Arm	147	4	2,72	143	97,28	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Prior anti-MM regimen	>1	SVd Arm	98	4	4,08	94	95,92	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Prior anti-MM regimen	1	SVd Arm	97	4	4,12	93	95,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline single cytogenetic alterations	N	SVd Arm	98	5	5,10	93	94,90	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline single cytogenetic alterations	Y	SVd Arm	97	3	3,09	94	96,91	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Previously Exposed to Bortezomib	N	SVd Arm	61	4	6,56	57	93,44	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Previously Exposed to Bortezomib	Y	SVd Arm	134	4	2,99	130	97,01	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Vomiting	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	total	-	SVd Arm	195	7	3,59	188	96,41	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	total	-	Vd Arm	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Gender	Female	SVd Arm	80	0	0,00	80	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Gender	Female	Vd Arm	91	0	0,00	91	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Gender	Male	SVd Arm	115	7	6,09	108	93,91	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Age Group	<65	SVd Arm	86	3	3,49	83	96,51	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Age Group	>=65	SVd Arm	109	4	3,67	105	96,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline R-ISS stage	Stage I or II	SVd Arm	173	6	3,47	167	96,53	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline ISS stage	Stage I or II	SVd Arm	163	6	3,68	157	96,32	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (SAP)	Region 2	SVd Arm	61	4	6,56	57	93,44	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (SAP)	Region 4	SVd Arm	69	2	2,90	67	97,10	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (by medical care situation)	Rest of the world	SVd Arm	78	3	3,85	75	96,15	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Race	Races other than White	SVd Arm	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Race	White	SVd Arm	161	6	3,73	155	96,27	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	5	2,92	166	97,08	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Prior PI therapies	N	SVd Arm	48	2	4,17	46	95,83	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Prior PI therapies	Y	SVd Arm	147	5	3,40	142	96,60	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Prior anti-MM regimen	>1	SVd Arm	98	3	3,06	95	96,94	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Prior anti-MM regimen	1	SVd Arm	97	4	4,12	93	95,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline single cytogenetic alterations	N	SVd Arm	98	7	7,14	91	92,86	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline single cytogenetic alterations	Y	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Previously Exposed to Bortezomib	N	SVd Arm	61	3	4,92	58	95,08	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Previously Exposed to Bortezomib	Y	SVd Arm	134	4	2,99	130	97,01	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Decreased Appetite	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	total	-	SVd Arm	195	5	2,56	190	97,44	NA	NA	NA	3,10	0,59	16,16	0,1587	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	total	-	Vd Arm	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Gender	Female	SVd Arm	80	2	2,50	78	97,50	NA	NA	NA	1,42	0,19	10,70	0,7341	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Gender	Female	Vd Arm	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Gender	Male	SVd Arm	115	3	2,61	112	97,39	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Age Group	<65	SVd Arm	86	2	2,33	84	97,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	NA	NA	NA	2,58	0,43	15,47	0,2827	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Age Group	>=65	Vd Arm	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline R-ISS stage	Stage I or II	SVd Arm	173	5	2,89	168	97,11	NA	NA	NA	2,71	0,53	14,00	0,2141	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline R-ISS stage	Stage I or II	Vd Arm	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline ISS stage	Stage I or II	SVd Arm	163	3	1,84	160	98,16	NA	NA	NA	1,64	0,27	9,81	0,5862	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline ISS stage	Stage I or II	Vd Arm	173	2	1,16	171	98,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (SAP)	Region 2	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (SAP)	Region 3	Vd Arm	53	2	3,77	51	96,23	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (SAP)	Region 4	SVd Arm	69	4	5,80	65	94,20	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	1	0,85	116	99,15	NA	NA	NA	0,52	0,05	5,78	0,5917	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (by medical care situation)	Rest of the world	SVd Arm	78	4	5,13	74	94,87	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Race	Races other than White	SVd Arm	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Race	White	SVd Arm	161	4	2,48	157	97,52	NA	NA	NA	1,85	0,34	10,13	0,4719	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Race	White	Vd Arm	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	4	2,34	167	97,66	NA	NA	NA	2,65	0,48	14,67	0,2458	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Prior PI therapies	Y	SVd Arm	147	5	3,40	142	96,60	NA	NA	NA	3,10	0,59	16,16	0,1587	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Prior PI therapies	Y	Vd Arm	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Prior anti-MM regimen	>1	SVd Arm	98	2	2,04	96	97,96	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Prior anti-MM regimen	1	SVd Arm	97	3	3,09	94	96,91	NA	NA	NA	1,67	0,28	10,00	0,5717	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline single cytogenetic alterations	N	SVd Arm	98	4	4,08	94	95,92	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline single cytogenetic alterations	Y	SVd Arm	97	1	1,03	96	98,97	NA	NA	NA	0,33	0,03	3,98	0,3657	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Baseline single cytogenetic alterations	Y	Vd Arm	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Previously Exposed to Bortezomib	N	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Previously Exposed to Bortezomib	Y	SVd Arm	134	5	3,73	129	96,27	NA	NA	NA	3,27	0,62	17,26	0,1403	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Weight Decreased	Previously Exposed to Bortezomib	Y	Vd Arm	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	total	-	SVd Arm	195	28	14,36	167	85,64	NA	NA	NA	1,20	0,70	2,07	0,5092	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	total	-	Vd Arm	204	25	12,25	179	87,75	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Gender	Female	SVd Arm	80	16	20,00	64	80,00	NA	34,50	NA	2,53	1,10	5,85	0,0251	0,0497
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Gender	Female	Vd Arm	91	11	12,09	80	87,91	NA	NA	NA	-	-	-	-	0,0497
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Gender	Male	SVd Arm	115	12	10,43	103	89,57	NA	NA	NA	0,81	0,37	1,75	0,5888	0,0497
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Gender	Male	Vd Arm	113	14	12,39	99	87,61	NA	NA	NA	-	-	-	-	0,0497
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Age Group	<65	SVd Arm	86	14	16,28	72	83,72	NA	NA	NA	1,82	0,72	4,63	0,2011	0,2891
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Age Group	<65	Vd Arm	75	7	9,33	68	90,67	NA	NA	NA	-	-	-	-	0,2891
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Age Group	>=65	SVd Arm	109	14	12,84	95	87,16	NA	NA	NA	0,97	0,48	1,96	0,9288	0,2891
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Age Group	>=65	Vd Arm	129	18	13,95	111	86,05	NA	NA	NA	-	-	-	-	0,2891
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	26	15,03	147	84,97	NA	NA	NA	1,21	0,68	2,16	0,5157	0,9402
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	21	12,07	153	87,93	NA	NA	NA	-	-	-	-	0,9402

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline R-ISS stage	Stage III	SVd Arm	12	2	16,67	10	83,33	NA	NA	NA	1,32	0,16	10,81	0,7972	0,9402
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline R-ISS stage	Stage III	Vd Arm	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,9402
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline ISS stage	Stage I or II	SVd Arm	163	17	10,43	146	89,57	NA	NA	NA	0,82	0,43	1,56	0,5437	0,0303
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline ISS stage	Stage I or II	Vd Arm	173	21	12,14	152	87,86	NA	NA	NA	-	-	-	-	0,0303
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline ISS stage	Stage III	SVd Arm	32	11	34,38	21	65,62	12,55	7,00	NA	3,58	1,11	11,51	0,0232	0,0303
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline ISS stage	Stage III	Vd Arm	31	4	12,90	27	87,10	20,90	20,90	NA	-	-	-	-	0,0303
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,7780
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	-	-	-	-	-	-	-	0,7780
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (SAP)	Region 2	SVd Arm	61	8	13,11	53	86,89	NA	34,50	NA	1,58	0,46	5,49	0,4665	0,7780
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (SAP)	Region 2	Vd Arm	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,7780
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (SAP)	Region 3	SVd Arm	47	7	14,89	40	85,11	NA	NA	NA	1,27	0,39	4,16	0,6884	0,7780
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (SAP)	Region 3	Vd Arm	53	6	11,32	47	88,68	NA	NA	NA	-	-	-	-	0,7780
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (SAP)	Region 4	SVd Arm	69	12	17,39	57	82,61	NA	NA	NA	0,95	0,43	2,09	0,9012	0,7780
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (SAP)	Region 4	Vd Arm	70	13	18,57	57	81,43	NA	NA	NA	-	-	-	-	0,7780
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	13	11,11	104	88,89	NA	NA	NA	1,06	0,48	2,32	0,8878	0,9306
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,9306
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (by medical care situation)	Rest of the world	SVd Arm	78	15	19,23	63	80,77	NA	NA	NA	1,11	0,52	2,40	0,7881	0,9306
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Region (by medical care situation)	Rest of the world	Vd Arm	68	12	17,65	56	82,35	NA	NA	NA	-	-	-	-	0,9306
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Race	Races other than White	SVd Arm	34	5	14,71	29	85,29	NA	NA	NA	2,36	0,53	10,52	0,2512	0,3167
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Race	Races other than White	Vd Arm	42	3	7,14	39	92,86	NA	NA	NA	-	-	-	-	0,3167
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Race	White	SVd Arm	161	23	14,29	138	85,71	NA	NA	NA	1,03	0,57	1,88	0,9124	0,3167
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Race	White	Vd Arm	162	22	13,58	140	86,42	NA	NA	NA	-	-	-	-	0,3167

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	24	14,04	147	85,96	NA	NA	NA	1,10	0,62	1,95	0,7457	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	24	12,97	161	87,03	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Prior PI therapies	N	SVd Arm	48	6	12,50	42	87,50	NA	NA	NA	1,20	0,36	4,01	0,7633	0,9976
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Prior PI therapies	N	Vd Arm	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,9976
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Prior PI therapies	Y	SVd Arm	147	22	14,97	125	85,03	NA	NA	NA	1,20	0,65	2,21	0,5570	0,9976
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Prior PI therapies	Y	Vd Arm	157	20	12,74	137	87,26	NA	NA	NA	-	-	-	-	0,9976
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Prior anti-MM regimen	>1	SVd Arm	98	16	16,33	82	83,67	NA	34,50	NA	1,50	0,71	3,20	0,2873	0,3961
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Prior anti-MM regimen	>1	Vd Arm	104	12	11,54	92	88,46	NA	NA	NA	-	-	-	-	0,3961
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Prior anti-MM regimen	1	SVd Arm	97	12	12,37	85	87,63	NA	NA	NA	0,94	0,42	2,07	0,8688	0,3961
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Prior anti-MM regimen	1	Vd Arm	100	13	13,00	87	87,00	NA	NA	NA	-	-	-	-	0,3961
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline single cytogenetic alterations	N	SVd Arm	98	11	11,22	87	88,78	NA	NA	NA	1,11	0,49	2,52	0,8120	0,7332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline single cytogenetic alterations	N	Vd Arm	111	12	10,81	99	89,19	NA	NA	NA	-	-	-	-	0,7332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline single cytogenetic alterations	Y	SVd Arm	97	17	17,53	80	82,47	NA	NA	NA	1,34	0,62	2,89	0,4483	0,7332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Baseline single cytogenetic alterations	Y	Vd Arm	93	13	13,98	80	86,02	NA	NA	NA	-	-	-	-	0,7332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Previously Exposed to Bortezomib	N	SVd Arm	61	8	13,11	53	86,89	NA	34,50	NA	1,20	0,36	4,01	0,7633	0,8730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Previously Exposed to Bortezomib	N	Vd Arm	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,8730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Previously Exposed to Bortezomib	Y	SVd Arm	134	20	14,93	114	85,07	NA	NA	NA	1,08	0,58	2,01	0,8162	0,8730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Pneumonia	Previously Exposed to Bortezomib	Y	Vd Arm	142	20	14,08	122	85,92	NA	NA	NA	-	-	-	-	0,8730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	total	-	SVd Arm	195	8	4,10	187	95,90	NA	NA	NA	4,14	0,87	19,68	0,0530	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	total	-	Vd Arm	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Gender	Female	SVd Arm	80	6	7,50	74	92,50	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Gender	Female	Vd Arm	91	1	1,10	90	98,90	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Gender	Male	SVd Arm	115	2	1,74	113	98,26	NA	NA	NA	2,09	0,19	23,10	0,5383	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Gender	Male	Vd Arm	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Age Group	<65	SVd Arm	86	4	4,65	82	95,35	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Age Group	>=65	SVd Arm	109	4	3,67	105	96,33	NA	NA	NA	2,50	0,44	14,10	0,2832	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Age Group	>=65	Vd Arm	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline R-ISS stage	Stage I or II	SVd Arm	173	7	4,05	166	95,95	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	NA	NA	NA	1,22	0,06	25,98	0,8964	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline ISS stage	Stage I or II	SVd Arm	163	6	3,68	157	96,32	NA	NA	NA	6,03	0,72	50,10	0,0582	0,5331
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	0,5331
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	NA	NA	NA	2,17	0,20	24,15	0,5174	0,5331
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,5331
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (SAP)	Region 2	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	0,89	0,12	6,51	0,9099	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (SAP)	Region 2	Vd Arm	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (SAP)	Region 3	SVd Arm	47	1	2,13	46	97,87	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (SAP)	Region 4	SVd Arm	69	5	7,25	64	92,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	3	2,56	114	97,44	NA	NA	NA	1,83	0,30	11,22	0,5058	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (by medical care situation)	Rest of the world	SVd Arm	78	5	6,41	73	93,59	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Race	Races other than White	SVd Arm	34	5	14,71	29	85,29	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Race	White	SVd Arm	161	3	1,86	158	98,14	NA	NA	NA	1,66	0,26	10,38	0,5856	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Race	White	Vd Arm	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	7	4,09	164	95,91	NA	NA	NA	4,11	0,82	20,69	0,0661	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	NA	NA	NA	1,31	0,08	22,28	0,8518	0,3637
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,3637
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Prior PI therapies	Y	SVd Arm	147	7	4,76	140	95,24	NA	NA	NA	6,71	0,82	54,57	0,0394	0,3637
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,3637
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Prior anti-MM regimen	>1	SVd Arm	98	7	7,14	91	92,86	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Prior anti-MM regimen	1	SVd Arm	97	1	1,03	96	98,97	NA	NA	NA	0,64	0,06	7,19	0,7123	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline single cytogenetic alterations	N	SVd Arm	98	6	6,12	92	93,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline single cytogenetic alterations	Y	SVd Arm	97	2	2,06	95	97,94	NA	NA	NA	1,50	0,13	16,79	0,7390	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Baseline single cytogenetic alterations	Y	Vd Arm	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	NA	NA	NA	0,89	0,07	10,91	0,9280	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Previously Exposed to Bortezomib	Y	SVd Arm	134	7	5,22	127	94,78	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Sepsis	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	total	-	SVd Arm	195	5	2,56	190	97,44	NA	NA	NA	1,81	0,43	7,64	0,4143	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	total	-	Vd Arm	204	3	1,47	201	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Gender	Female	SVd Arm	80	3	3,75	77	96,25	NA	NA	NA	3,67	0,38	35,58	0,2292	0,4151
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Gender	Female	Vd Arm	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,4151
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Gender	Male	SVd Arm	115	2	1,74	113	98,26	NA	NA	NA	1,04	0,14	7,85	0,9714	0,4151
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Gender	Male	Vd Arm	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,4151
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Age Group	<65	SVd Arm	86	1	1,16	85	98,84	NA	NA	NA	0,25	0,02	2,82	0,2256	0,0573
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Age Group	<65	Vd Arm	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,0573
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Age Group	>=65	SVd Arm	109	4	3,67	105	96,33	NA	NA	NA	6,02	0,66	55,24	0,0739	0,0573
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	0,0573
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline R-ISS stage	Stage I or II	SVd Arm	173	4	2,31	169	97,69	NA	NA	NA	1,98	0,36	10,86	0,4238	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline R-ISS stage	Stage I or II	Vd Arm	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline ISS stage	Stage I or II	SVd Arm	163	4	2,45	159	97,55	NA	NA	NA	1,43	0,32	6,38	0,6401	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline ISS stage	Stage I or II	Vd Arm	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,9727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,9727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (SAP)	Region 2	SVd Arm	61	2	3,28	59	96,72	NA	25,23	NA	2,68	0,22	33,12	0,4297	0,9727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (SAP)	Region 2	Vd Arm	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,9727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,9727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	0,9727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (SAP)	Region 4	SVd Arm	69	3	4,35	66	95,65	NA	NA	NA	2,84	0,29	27,43	0,3458	0,9727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (SAP)	Region 4	Vd Arm	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,9727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	2	1,71	115	98,29	NA	NA	NA	1,32	0,17	10,01	0,7891	0,6993
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	0,6993
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (by medical care situation)	Rest of the world	SVd Arm	78	3	3,85	75	96,15	NA	NA	NA	2,40	0,25	23,10	0,4344	0,6993
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Region (by medical care situation)	Rest of the world	Vd Arm	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,6993
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Race	Races other than White	SVd Arm	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Race	White	SVd Arm	161	4	2,48	157	97,52	NA	NA	NA	1,45	0,31	6,71	0,6304	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Race	White	Vd Arm	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	3	1,75	168	98,25	NA	NA	NA	1,07	0,21	5,30	0,9368	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	3	1,62	182	98,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	NA	NA	NA	0,92	0,06	14,79	0,9524	0,5826
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,5826
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Prior PI therapies	Y	SVd Arm	147	4	2,72	143	97,28	NA	NA	NA	2,29	0,42	12,67	0,3278	0,5826
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Prior PI therapies	Y	Vd Arm	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,5826
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Prior anti-MM regimen	>1	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	1,54	0,26	9,24	0,6362	0,7738
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Prior anti-MM regimen	>1	Vd Arm	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	0,7738
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Prior anti-MM regimen	1	SVd Arm	97	2	2,06	95	97,94	NA	NA	NA	2,39	0,21	27,13	0,4684	0,7738
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,7738
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline single cytogenetic alterations	N	SVd Arm	98	4	4,08	94	95,92	NA	NA	NA	2,63	0,44	15,63	0,2730	0,4864
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline single cytogenetic alterations	N	Vd Arm	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,4864
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline single cytogenetic alterations	Y	SVd Arm	97	1	1,03	96	98,97	NA	NA	NA	0,82	0,05	13,06	0,8859	0,4864
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,4864
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	NA	NA	NA	0,92	0,06	14,79	0,9524	0,5562
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,5562
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Previously Exposed to Bortezomib	Y	SVd Arm	134	4	2,99	130	97,01	NA	NA	NA	2,45	0,44	13,58	0,2904	0,5562
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Opportunistic Infection	Previously Exposed to Bortezomib	Y	Vd Arm	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,5562
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	total	-	SVd Arm	195	2	1,03	193	98,97	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	total	-	Vd Arm	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Gender	Female	SVd Arm	80	0	0,00	80	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Gender	Female	Vd Arm	91	0	0,00	91	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Gender	Male	SVd Arm	115	2	1,74	113	98,26	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Age Group	<65	SVd Arm	86	1	1,16	85	98,84	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Age Group	>=65	SVd Arm	109	1	0,92	108	99,08	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline R-ISS stage	Stage I or II	SVd Arm	173	2	1,16	171	98,84	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline ISS stage	Stage I or II	SVd Arm	163	2	1,23	161	98,77	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (SAP)	Region 2	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (SAP)	Region 4	SVd Arm	69	1	1,45	68	98,55	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	1	0,85	116	99,15	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (by medical care situation)	Rest of the world	SVd Arm	78	1	1,28	77	98,72	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Race	Races other than White	SVd Arm	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Race	White	SVd Arm	161	1	0,62	160	99,38	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	2	1,17	169	98,83	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Prior PI therapies	Y	SVd Arm	147	2	1,36	145	98,64	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Prior anti-MM regimen	>1	SVd Arm	98	1	1,02	97	98,98	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Prior anti-MM regimen	1	SVd Arm	97	1	1,03	96	98,97	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline single cytogenetic alterations	N	SVd Arm	98	2	2,04	96	97,96	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline single cytogenetic alterations	Y	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Previously Exposed to Bortezomib	N	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Previously Exposed to Bortezomib	Y	SVd Arm	134	2	1,49	132	98,51	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Blurred Vision	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	total	-	SVd Arm	195	22	11,28	173	88,72	NA	30,95	NA	5,83	1,98	17,14	0,0003	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	total	-	Vd Arm	204	4	1,96	200	98,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Gender	Female	SVd Arm	80	8	10,00	72	90,00	NA	NA	NA	7,82	0,92	66,31	0,0293	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Gender	Female	Vd Arm	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Gender	Male	SVd Arm	115	14	12,17	101	87,83	NA	26,91	NA	4,22	1,18	15,08	0,0167	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Gender	Male	Vd Arm	113	3	2,65	110	97,35	NA	NA	NA	-	-	-	-	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Age Group	<65	SVd Arm	86	14	16,28	72	83,72	30,95	20,30	NA	3,41	0,94	12,47	0,0492	0,3849
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Age Group	<65	Vd Arm	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,3849
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Age Group	>=65	SVd Arm	109	8	7,34	101	92,66	NA	NA	NA	10,15	1,26	81,93	0,0076	0,3849
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	0,3849
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline R-ISS stage	Stage I or II	SVd Arm	173	21	12,14	152	87,86	NA	NA	NA	4,98	1,69	14,64	0,0013	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline R-ISS stage	Stage I or II	Vd Arm	174	4	2,30	170	97,70	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline ISS stage	Stage I or II	SVd Arm	163	20	12,27	143	87,73	NA	30,95	NA	5,24	1,78	15,43	0,0008	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline ISS stage	Stage I or II	Vd Arm	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (SAP)	Region 1	SVd Arm	18	4	22,22	14	77,78	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (SAP)	Region 2	SVd Arm	61	8	13,11	53	86,89	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (SAP)	Region 3	SVd Arm	47	2	4,26	45	95,74	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (SAP)	Region 4	SVd Arm	69	8	11,59	61	88,41	NA	26,91	NA	2,70	0,67	10,91	0,1482	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (SAP)	Region 4	Vd Arm	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	10	8,55	107	91,45	NA	NA	NA	10,81	1,37	85,29	0,0050	0,4756
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,4756
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (by medical care situation)	Rest of the world	SVd Arm	78	12	15,38	66	84,62	NA	25,82	NA	4,44	1,20	16,41	0,0156	0,4756
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Region (by medical care situation)	Rest of the world	Vd Arm	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,4756
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Race	Races other than White	SVd Arm	34	3	8,82	31	91,18	NA	NA	NA	1,17	0,11	12,98	0,8967	0,1754
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Race	Races other than White	Vd Arm	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,1754
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Race	White	SVd Arm	161	19	11,80	142	88,20	NA	30,95	NA	8,23	1,89	35,88	0,0009	0,1754
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Race	White	Vd Arm	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	0,1754
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	18	10,53	153	89,47	NA	30,95	NA	4,93	1,64	14,81	0,0017	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	4	2,16	181	97,84	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Prior PI therapies	N	SVd Arm	48	7	14,58	41	85,42	NA	NA	NA	2,65	0,51	13,71	0,2279	0,2744
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Prior PI therapies	N	Vd Arm	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,2744
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Prior PI therapies	Y	SVd Arm	147	15	10,20	132	89,80	NA	25,82	NA	9,10	2,07	40,02	0,0004	0,2744
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Prior PI therapies	Y	Vd Arm	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,2744
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Prior anti-MM regimen	>1	SVd Arm	98	13	13,27	85	86,73	NA	25,82	NA	4,90	1,38	17,46	0,0067	0,6539
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Prior anti-MM regimen	>1	Vd Arm	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,6539
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Prior anti-MM regimen	1	SVd Arm	97	9	9,28	88	90,72	NA	NA	NA	8,57	1,06	69,04	0,0163	0,6539
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,6539
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline single cytogenetic alterations	N	SVd Arm	98	11	11,22	87	88,78	NA	30,95	NA	5,77	1,21	27,49	0,0143	0,8530
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline single cytogenetic alterations	N	Vd Arm	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,8530
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline single cytogenetic alterations	Y	SVd Arm	97	11	11,34	86	88,66	NA	25,82	NA	4,69	1,02	21,51	0,0295	0,8530
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Baseline single cytogenetic alterations	Y	Vd Arm	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,8530
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Previously Exposed to Bortezomib	N	SVd Arm	61	11	18,03	50	81,97	NA	26,91	NA	3,16	0,64	15,71	0,1390	0,5111
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,5111
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Previously Exposed to Bortezomib	Y	SVd Arm	134	11	8,21	123	91,79	NA	30,95	NA	6,62	1,46	30,09	0,0049	0,5111
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cataract	Previously Exposed to Bortezomib	Y	Vd Arm	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,5111
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	total	-	SVd Arm	195	10	5,13	185	94,87	NA	NA	NA	10,70	1,37	83,73	0,0048	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	total	-	Vd Arm	204	1	0,49	203	99,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Gender	Female	SVd Arm	80	6	7,50	74	92,50	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Gender	Male	SVd Arm	115	4	3,48	111	96,52	NA	NA	NA	3,89	0,43	34,88	0,1900	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Gender	Male	Vd Arm	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Age Group	<65	SVd Arm	86	5	5,81	81	94,19	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Age Group	>=65	SVd Arm	109	5	4,59	104	95,41	NA	NA	NA	4,84	0,56	41,53	0,1115	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	7	4,05	166	95,95	NA	NA	NA	6,85	0,84	55,82	0,0371	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline R-ISS stage	Stage III	SVd Arm	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline ISS stage	Stage I or II	SVd Arm	163	5	3,07	158	96,93	NA	NA	NA	4,93	0,58	42,25	0,1064	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline ISS stage	Stage III	SVd Arm	32	5	15,62	27	84,38	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (SAP)	Region 2	SVd Arm	61	4	6,56	57	93,44	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (SAP)	Region 4	SVd Arm	69	5	7,25	64	92,75	NA	NA	NA	5,71	0,66	49,02	0,0731	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (SAP)	Region 4	Vd Arm	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (by medical care situation)	Rest of the world	SVd Arm	78	6	7,69	72	92,31	NA	NA	NA	5,19	0,62	43,35	0,0905	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Region (by medical care situation)	Rest of the world	Vd Arm	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	3,53	0,32	39,17	0,2726	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Race	White	SVd Arm	161	8	4,97	153	95,03	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	10	5,85	161	94,15	NA	NA	NA	10,86	1,39	85,07	0,0045	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	1	0,54	184	99,46	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Prior PI therapies	N	SVd Arm	48	2	4,17	46	95,83	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Prior PI therapies	Y	SVd Arm	147	8	5,44	139	94,56	NA	NA	NA	8,79	1,10	70,44	0,0135	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Prior anti-MM regimen	>1	SVd Arm	98	6	6,12	92	93,88	NA	NA	NA	6,47	0,78	53,88	0,0470	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Prior anti-MM regimen	>1	Vd Arm	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Prior anti-MM regimen	1	SVd Arm	97	4	4,12	93	95,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	3,54	0,37	34,08	0,2419	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline single cytogenetic alterations	N	Vd Arm	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline single cytogenetic alterations	Y	SVd Arm	97	7	7,22	90	92,78	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Previously Exposed to Bortezomib	N	SVd Arm	61	2	3,28	59	96,72	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Previously Exposed to Bortezomib	Y	SVd Arm	134	8	5,97	126	94,03	NA	NA	NA	9,01	1,12	72,43	0,0125	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hyponatraemia	Previously Exposed to Bortezomib	Y	Vd Arm	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	total	-	SVd Arm	195	8	4,10	187	95,90	NA	NA	NA	3,57	0,74	17,24	0,0900	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	total	-	Vd Arm	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Gender	Female	SVd Arm	80	1	1,25	79	98,75	NA	NA	NA	1,26	0,08	20,22	0,8681	0,3954
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Gender	Female	Vd Arm	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,3954
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Gender	Male	SVd Arm	115	7	6,09	108	93,91	NA	NA	NA	5,74	0,69	47,75	0,0674	0,3954
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Gender	Male	Vd Arm	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	0,3954
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Age Group	<65	SVd Arm	86	2	2,33	84	97,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Age Group	>=65	SVd Arm	109	6	5,50	103	94,50	NA	NA	NA	3,38	0,65	17,55	0,1244	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Age Group	>=65	Vd Arm	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline R-ISS stage	Stage I or II	SVd Arm	173	6	3,47	167	96,53	NA	NA	NA	3,17	0,64	15,72	0,1360	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline R-ISS stage	Stage I or II	Vd Arm	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline ISS stage	Stage I or II	SVd Arm	163	7	4,29	156	95,71	NA	NA	NA	3,69	0,77	17,77	0,0810	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline ISS stage	Stage I or II	Vd Arm	173	2	1,16	171	98,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (SAP)	Region 1	SVd Arm	18	2	11,11	16	88,89	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (SAP)	Region 2	SVd Arm	61	3	4,92	58	95,08	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (SAP)	Region 4	SVd Arm	69	3	4,35	66	95,65	NA	NA	NA	0,93	0,13	6,64	0,9438	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (SAP)	Region 4	Vd Arm	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	NA	NA	NA	4,86	0,54	43,93	0,1202	0,6873
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,6873
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (by medical care situation)	Rest of the world	SVd Arm	78	4	5,13	74	94,87	NA	NA	NA	2,54	0,26	24,48	0,4033	0,6873
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Region (by medical care situation)	Rest of the world	Vd Arm	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,6873
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Race	Races other than White	SVd Arm	34	3	8,82	31	91,18	NA	NA	NA	3,65	0,33	40,73	0,2610	0,8596
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,8596
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Race	White	SVd Arm	161	5	3,11	156	96,89	NA	NA	NA	4,89	0,57	42,21	0,1112	0,8596
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Race	White	Vd Arm	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	0,8596
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	7	4,09	164	95,91	NA	NA	NA	3,13	0,63	15,58	0,1415	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Prior PI therapies	Y	SVd Arm	147	8	5,44	139	94,56	NA	NA	NA	3,57	0,74	17,24	0,0900	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Prior PI therapies	Y	Vd Arm	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Prior anti-MM regimen	>1	SVd Arm	98	5	5,10	93	94,90	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Prior anti-MM regimen	1	SVd Arm	97	3	3,09	94	96,91	NA	NA	NA	1,54	0,26	9,23	0,6328	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline single cytogenetic alterations	N	SVd Arm	98	6	6,12	92	93,88	NA	NA	NA	5,76	0,67	49,45	0,0707	0,4969
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline single cytogenetic alterations	N	Vd Arm	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	0,4969
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline single cytogenetic alterations	Y	SVd Arm	97	2	2,06	95	97,94	NA	NA	NA	1,88	0,17	20,88	0,5998	0,4969
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,4969
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Previously Exposed to Bortezomib	Y	SVd Arm	134	7	5,22	127	94,78	NA	NA	NA	5,74	0,69	47,72	0,0670	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neurological Toxicity	Previously Exposed to Bortezomib	Y	Vd Arm	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	total	-	SVd Arm	195	7	3,59	188	96,41	NA	NA	NA	0,90	0,32	2,49	0,8357	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	total	-	Vd Arm	204	8	3,92	196	96,08	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Gender	Female	SVd Arm	80	2	2,50	78	97,50	NA	NA	NA	0,61	0,10	3,66	0,5828	0,6600
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Gender	Female	Vd Arm	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,6600
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Gender	Male	SVd Arm	115	5	4,35	110	95,65	NA	NA	NA	0,99	0,28	3,47	0,9909	0,6600
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Gender	Male	Vd Arm	113	5	4,42	108	95,58	NA	NA	NA	-	-	-	-	0,6600
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Age Group	<65	SVd Arm	86	3	3,49	83	96,51	NA	NA	NA	1,21	0,24	6,14	0,8215	0,7585
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Age Group	<65	Vd Arm	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,7585

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Age Group	>=65	SVd Arm	109	4	3,67	105	96,33	NA	NA	NA	0,87	0,23	3,27	0,8334	0,7585
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Age Group	>=65	Vd Arm	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,7585
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline R-ISS stage	Stage I or II	SVd Arm	173	6	3,47	167	96,53	NA	NA	NA	0,81	0,27	2,43	0,7128	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline R-ISS stage	Stage I or II	Vd Arm	174	7	4,02	167	95,98	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline ISS stage	Stage I or II	SVd Arm	163	7	4,29	156	95,71	NA	NA	NA	1,36	0,43	4,29	0,5967	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline ISS stage	Stage I or II	Vd Arm	173	5	2,89	168	97,11	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline ISS stage	Stage III	Vd Arm	31	3	9,68	28	90,32	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,2549
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	0,2549
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (SAP)	Region 2	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	0,48	0,08	3,00	0,4247	0,2549
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (SAP)	Region 2	Vd Arm	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,2549
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (SAP)	Region 3	SVd Arm	47	2	4,26	45	95,74	NA	NA	NA	0,34	0,06	1,91	0,1992	0,2549
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (SAP)	Region 3	Vd Arm	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,2549
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (SAP)	Region 4	SVd Arm	69	3	4,35	66	95,65	NA	NA	NA	3,45	0,36	33,30	0,2548	0,2549
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (SAP)	Region 4	Vd Arm	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,2549
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	NA	NA	NA	0,64	0,19	2,20	0,4764	0,2630
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	7	5,15	129	94,85	NA	NA	NA	-	-	-	-	0,2630
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (by medical care situation)	Rest of the world	SVd Arm	78	3	3,85	75	96,15	NA	NA	NA	2,83	0,29	27,97	0,3533	0,2630
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Region (by medical care situation)	Rest of the world	Vd Arm	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,2630

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Race	White	SVd Arm	161	7	4,35	154	95,65	NA	NA	NA	0,86	0,30	2,51	0,7843	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Race	White	Vd Arm	162	7	4,32	155	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	6	3,51	165	96,49	NA	NA	NA	0,79	0,27	2,30	0,6703	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	8	4,32	177	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Prior PI therapies	Y	SVd Arm	147	6	4,08	141	95,92	NA	NA	NA	0,78	0,27	2,25	0,6403	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Prior PI therapies	Y	Vd Arm	157	8	5,10	149	94,90	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Prior anti-MM regimen	>1	SVd Arm	98	4	4,08	94	95,92	NA	NA	NA	0,65	0,18	2,32	0,5072	0,3962
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Prior anti-MM regimen	>1	Vd Arm	104	6	5,77	98	94,23	NA	NA	NA	-	-	-	-	0,3962
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Prior anti-MM regimen	1	SVd Arm	97	3	3,09	94	96,91	NA	NA	NA	1,69	0,28	10,19	0,5618	0,3962
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,3962
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	0,97	0,21	4,39	0,9642	0,8139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline single cytogenetic alterations	N	Vd Arm	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,8139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline single cytogenetic alterations	Y	SVd Arm	97	4	4,12	93	95,88	NA	NA	NA	0,75	0,19	3,04	0,6909	0,8139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Baseline single cytogenetic alterations	Y	Vd Arm	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,8139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Previously Exposed to Bortezomib	N	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	1,50	0,13	17,68	0,7478	0,6485
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,6485

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Previously Exposed to Bortezomib	Y	SVd Arm	134	5	3,73	129	96,27	NA	NA	NA	0,79	0,25	2,52	0,6939	0,6485
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Hepatobiliary Disorders	Previously Exposed to Bortezomib	Y	Vd Arm	142	7	4,93	135	95,07	NA	NA	NA	-	-	-	-	0,6485
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	total	-	SVd Arm	195	3	1,54	192	98,46	NA	NA	NA	2,45	0,25	24,10	0,4283	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	total	-	Vd Arm	204	1	0,49	203	99,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Gender	Female	SVd Arm	80	2	2,50	78	97,50	NA	NA	NA	2,30	0,20	26,65	0,4941	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Gender	Female	Vd Arm	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Gender	Male	SVd Arm	115	1	0,87	114	99,13	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Age Group	<65	SVd Arm	86	0	0,00	86	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	NA	NA	NA	2,35	0,24	22,86	0,4491	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline R-ISS stage	Stage I or II	SVd Arm	173	3	1,73	170	98,27	NA	NA	NA	2,33	0,23	23,16	0,4572	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline R-ISS stage	Stage I or II	Vd Arm	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline ISS stage	Stage I or II	SVd Arm	163	3	1,84	160	98,16	NA	NA	NA	2,48	0,25	24,32	0,4198	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (SAP)	Region 2	SVd Arm	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (SAP)	Region 3	SVd Arm	47	2	4,26	45	95,74	NA	NA	NA	1,43	0,11	18,51	0,7813	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (SAP)	Region 3	Vd Arm	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (SAP)	Region 4	SVd Arm	69	0	0,00	69	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	3	2,56	114	97,44	NA	NA	NA	2,69	0,27	26,83	0,3831	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (by medical care situation)	Rest of the world	SVd Arm	78	0	0,00	78	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Race	White	SVd Arm	161	3	1,86	158	98,14	NA	NA	NA	2,10	0,21	21,04	0,5178	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Race	White	Vd Arm	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	3	1,75	168	98,25	NA	NA	NA	2,54	0,26	24,86	0,4066	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	1	0,54	184	99,46	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Prior PI therapies	Y	SVd Arm	147	2	1,36	145	98,64	NA	NA	NA	1,95	0,18	21,54	0,5787	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Prior anti-MM regimen	>1	SVd Arm	98	2	2,04	96	97,96	NA	NA	NA	1,95	0,18	21,54	0,5787	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Prior anti-MM regimen	>1	Vd Arm	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Prior anti-MM regimen	1	SVd Arm	97	1	1,03	96	98,97	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline single cytogenetic alterations	N	SVd Arm	98	1	1,02	97	98,98	NA	NA	NA	0,58	0,03	11,02	0,7137	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline single cytogenetic alterations	N	Vd Arm	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline single cytogenetic alterations	Y	SVd Arm	97	2	2,06	95	97,94	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Previously Exposed to Bortezomib	N	SVd Arm	61	3	4,92	58	95,08	NA	NA	NA	0,71	0,04	12,46	0,8121	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Previously Exposed to Bortezomib	Y	SVd Arm	134	0	0,00	134	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Cardiac Toxicity	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	NA	NA	NA	-	-	-	-	NA
~~Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue~~	~~total~~	-	~~SVd Arm~~	~~195~~	~~40~~	~~20,51~~	~~155~~	~~79,49~~	~~NA~~	~~NA~~	~~NA~~	~~4,03~~	~~2,05~~	~~7,89~~	~~0,0000~~	~~NA~~
~~Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue~~	~~total~~	-	~~Vd Arm~~	~~204~~	~~11~~	~~5,39~~	~~193~~	~~94,61~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	~~NA~~
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Gender	Female	SVd Arm	80	16	20,00	64	80,00	NA	NA	NA	4,02	1,34	12,09	0,0076	0,7856
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Gender	Female	Vd Arm	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,7856
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Gender	Male	SVd Arm	115	24	20,87	91	79,13	NA	NA	NA	3,31	1,42	7,71	0,0032	0,7856
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Gender	Male	Vd Arm	113	7	6,19	106	93,81	NA	NA	NA	-	-	-	-	0,7856
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Age Group	<65	SVd Arm	86	12	13,95	74	86,05	NA	NA	NA	6,45	1,38	30,04	0,0078	0,6190
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Age Group	<65	Vd Arm	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,6190
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Age Group	>=65	SVd Arm	109	28	25,69	81	74,31	NA	NA	NA	4,17	1,95	8,91	0,0001	0,6190
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Age Group	>=65	Vd Arm	129	9	6,98	120	93,02	NA	NA	NA	-	-	-	-	0,6190

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline R-ISS stage	Stage I or II	SVd Arm	173	38	21,97	135	78,03	NA	NA	NA	4,34	2,09	8,98	0,0000	0,6413
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline R-ISS stage	Stage I or II	Vd Arm	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	0,6413
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline R-ISS stage	Stage III	SVd Arm	12	2	16,67	10	83,33	NA	NA	NA	2,28	0,17	30,72	0,5271	0,6413
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	13,31	NA	-	-	-	-	0,6413
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline ISS stage	Stage I or II	SVd Arm	163	33	20,25	130	79,75	NA	NA	NA	4,00	1,91	8,36	0,0001	0,9618
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline ISS stage	Stage I or II	Vd Arm	173	9	5,20	164	94,80	NA	NA	NA	-	-	-	-	0,9618
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline ISS stage	Stage III	SVd Arm	32	7	21,88	25	78,12	NA	NA	NA	4,17	0,85	20,58	0,0581	0,9618
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline ISS stage	Stage III	Vd Arm	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,9618
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (SAP)	Region 1	SVd Arm	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,1986
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,1986
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (SAP)	Region 2	SVd Arm	61	11	18,03	50	81,97	NA	NA	NA	1,44	0,57	3,62	0,4338	0,1986
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (SAP)	Region 2	Vd Arm	64	8	12,50	56	87,50	NA	NA	NA	-	-	-	-	0,1986
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (SAP)	Region 3	SVd Arm	47	15	31,91	32	68,09	-	-	-	-	-	-	-	0,1986
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,1986
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (SAP)	Region 4	SVd Arm	69	11	15,94	58	84,06	NA	NA	NA	4,09	1,12	14,90	0,0215	0,1986
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (SAP)	Region 4	Vd Arm	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	0,1986
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	25	21,37	92	78,63	NA	NA	NA	4,29	1,83	10,05	0,0003	0,8504
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	7	5,15	129	94,85	NA	NA	NA	-	-	-	-	0,8504
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (by medical care situation)	Rest of the world	SVd Arm	78	15	19,23	63	80,77	NA	NA	NA	3,75	1,22	11,49	0,0137	0,8504
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Region (by medical care situation)	Rest of the world	Vd Arm	68	4	5,88	64	94,12	NA	NA	NA	-	-	-	-	0,8504
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Race	Races other than White	SVd Arm	34	6	17,65	28	82,35	NA	NA	NA	1,56	0,45	5,44	0,4782	0,0815
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Race	Races other than White	Vd Arm	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,0815

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Race	White	SVd Arm	161	34	21,12	127	78,88	NA	NA	NA	6,07	2,52	14,66	0,0000	0,0815
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Race	White	Vd Arm	162	6	3,70	156	96,30	NA	NA	NA	-	-	-	-	0,0815
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	36	21,05	135	78,95	NA	NA	NA	4,10	2,02	8,32	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	10	5,41	175	94,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Prior PI therapies	N	SVd Arm	48	10	20,83	38	79,17	NA	NA	NA	3,96	1,06	14,82	0,0286	0,9773
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Prior PI therapies	N	Vd Arm	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,9773
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Prior PI therapies	Y	SVd Arm	147	30	20,41	117	79,59	NA	NA	NA	4,05	1,85	8,85	0,0001	0,9773
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Prior PI therapies	Y	Vd Arm	157	8	5,10	149	94,90	NA	NA	NA	-	-	-	-	0,9773
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Prior anti-MM regimen	>1	SVd Arm	98	19	19,39	79	80,61	NA	NA	NA	4,95	1,68	14,56	0,0013	0,6153
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Prior anti-MM regimen	>1	Vd Arm	104	4	3,85	100	96,15	NA	NA	NA	-	-	-	-	0,6153
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Prior anti-MM regimen	1	SVd Arm	97	21	21,65	76	78,35	NA	NA	NA	3,47	1,46	8,26	0,0028	0,6153
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Prior anti-MM regimen	1	Vd Arm	100	7	7,00	93	93,00	NA	NA	NA	-	-	-	-	0,6153
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline single cytogenetic alterations	N	SVd Arm	98	21	21,43	77	78,57	NA	NA	NA	3,93	1,65	9,38	0,0009	0,9769
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline single cytogenetic alterations	N	Vd Arm	111	7	6,31	104	93,69	NA	NA	NA	-	-	-	-	0,9769
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline single cytogenetic alterations	Y	SVd Arm	97	19	19,59	78	80,41	NA	NA	NA	4,02	1,36	11,85	0,0065	0,9769
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Baseline single cytogenetic alterations	Y	Vd Arm	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,9769
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Previously Exposed to Bortezomib	N	SVd Arm	61	13	21,31	48	78,69	NA	NA	NA	3,90	1,24	12,27	0,0131	0,9183
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Previously Exposed to Bortezomib	N	Vd Arm	62	4	6,45	58	93,55	NA	NA	NA	-	-	-	-	0,9183
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Previously Exposed to Bortezomib	Y	SVd Arm	134	27	20,15	107	79,85	NA	NA	NA	4,20	1,82	9,66	0,0002	0,9183
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Fatigue	Previously Exposed to Bortezomib	Y	Vd Arm	142	7	4,93	135	95,07	NA	NA	NA	-	-	-	-	0,9183

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
~~Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages~~	~~total~~	-	~~SVd Arm~~	~~195~~	~~5~~	~~2,56~~	~~190~~	~~97,44~~	~~NA~~	~~NA~~	~~NA~~	~~1,93~~	~~0,45~~	~~8,30~~	~~0,3684~~	~~NA~~
~~Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages~~	~~total~~	-	~~Vd Arm~~	~~204~~	~~3~~	~~1,47~~	~~201~~	~~98,53~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	~~NA~~
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Gender	Female	SVd Arm	80	2	2,50	78	97,50	NA	NA	NA	1,59	0,14	17,95	0,7044	0,7322
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Gender	Female	Vd Arm	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,7322
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Gender	Male	SVd Arm	115	3	2,61	112	97,39	NA	NA	NA	2,84	0,30	27,32	0,3445	0,7322
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Gender	Male	Vd Arm	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	0,7322
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Age Group	<65	SVd Arm	86	3	3,49	83	96,51	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Age Group	>=65	SVd Arm	109	2	1,83	107	98,17	NA	NA	NA	0,90	0,15	5,45	0,9097	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Age Group	>=65	Vd Arm	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline R-ISS stage	Stage I or II	SVd Arm	173	5	2,89	168	97,11	NA	NA	NA	1,64	0,39	6,89	0,4948	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline R-ISS stage	Stage I or II	Vd Arm	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline ISS stage	Stage I or II	SVd Arm	163	4	2,45	159	97,55	NA	NA	NA	1,35	0,30	6,03	0,6955	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline ISS stage	Stage I or II	Vd Arm	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	NA	NA	NA	0,50	0,03	8,46	0,6250	0,4437
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	NA	10,78	NA	-	-	-	-	0,4437
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (SAP)	Region 2	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	2,13	0,19	23,63	0,5270	0,4437
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (SAP)	Region 2	Vd Arm	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,4437

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,4437
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	0,4437
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (SAP)	Region 4	SVd Arm	69	2	2,90	67	97,10	-	-	-	-	-	-	-	0,4437
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	0,4437
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	2	1,71	115	98,29	NA	NA	NA	0,88	0,14	5,60	0,8935	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	3	2,21	133	97,79	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (by medical care situation)	Rest of the world	SVd Arm	78	3	3,85	75	96,15	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	3,15	0,26	38,03	0,3461	0,6179
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,6179
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Race	White	SVd Arm	161	3	1,86	158	98,14	NA	NA	NA	1,44	0,24	8,70	0,6873	0,6179
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Race	White	Vd Arm	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	0,6179
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	4	2,34	167	97,66	NA	NA	NA	2,46	0,43	13,98	0,2973	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	NA	NA	NA	0,95	0,06	15,17	0,9682	0,5602
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,5602
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Prior PI therapies	Y	SVd Arm	147	4	2,72	143	97,28	NA	NA	NA	2,50	0,44	14,18	0,2857	0,5602
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Prior PI therapies	Y	Vd Arm	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,5602
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Prior anti-MM regimen	>1	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	4,02	0,39	41,33	0,2114	0,3851
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Prior anti-MM regimen	>1	Vd Arm	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	0,3851

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Prior anti-MM regimen	1	SVd Arm	97	2	2,06	95	97,94	NA	NA	NA	1,04	0,15	7,43	0,9675	0,3851
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,3851
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline single cytogenetic alterations	Y	SVd Arm	97	2	2,06	95	97,94	NA	NA	NA	0,71	0,11	4,43	0,7101	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Baseline single cytogenetic alterations	Y	Vd Arm	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	NA	NA	NA	0,95	0,06	15,17	0,9682	0,5235
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,5235
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Previously Exposed to Bortezomib	Y	SVd Arm	134	4	2,99	130	97,01	NA	NA	NA	2,78	0,46	16,80	0,2508	0,5235
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Haemorrhages	Previously Exposed to Bortezomib	Y	Vd Arm	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,5235
~~Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral~~	~~total~~	-	~~SVd Arm~~	~~195~~	~~9~~	~~4,62~~	~~186~~	~~95,38~~	~~NA~~	~~NA~~	~~NA~~	~~0,50~~	~~0,22~~	~~1,11~~	~~0,0809~~	~~NA~~
~~Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral~~	~~total~~	-	~~Vd Arm~~	~~204~~	~~18~~	~~8,82~~	~~186~~	~~91,18~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	~~NA~~
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Gender	Female	SVd Arm	80	7	8,75	73	91,25	NA	NA	NA	1,23	0,40	3,76	0,7112	0,0316
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Gender	Female	Vd Arm	91	6	6,59	85	93,41	NA	NA	NA	-	-	-	-	0,0316
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Gender	Male	SVd Arm	115	2	1,74	113	98,26	NA	NA	NA	0,16	0,04	0,71	0,0059	0,0316
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Gender	Male	Vd Arm	113	12	10,62	101	89,38	NA	NA	NA	-	-	-	-	0,0316
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Age Group	<65	SVd Arm	86	4	4,65	82	95,35	NA	NA	NA	1,05	0,23	4,78	0,9511	0,2584
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Age Group	<65	Vd Arm	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,2584
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Age Group	>=65	SVd Arm	109	5	4,59	104	95,41	NA	NA	NA	0,37	0,13	1,02	0,0449	0,2584
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Age Group	>=65	Vd Arm	129	15	11,63	114	88,37	NA	NA	NA	-	-	-	-	0,2584
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline R-ISS stage	Stage I or II	SVd Arm	173	9	5,20	164	94,80	NA	NA	NA	0,62	0,27	1,43	0,2575	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline R-ISS stage	Stage I or II	Vd Arm	174	14	8,05	160	91,95	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline R-ISS stage	Stage III	Vd Arm	16	2	12,50	14	87,50	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline ISS stage	Stage I or II	SVd Arm	163	8	4,91	155	95,09	NA	NA	NA	0,68	0,28	1,65	0,3873	0,2925
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline ISS stage	Stage I or II	Vd Arm	173	12	6,94	161	93,06	NA	NA	NA	-	-	-	-	0,2925
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	NA	NA	NA	0,19	0,02	1,66	0,0981	0,2925
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline ISS stage	Stage III	Vd Arm	31	6	19,35	25	80,65	NA	16,76	NA	-	-	-	-	0,2925
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,7350
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	0,7350
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (SAP)	Region 2	SVd Arm	61	3	4,92	58	95,08	NA	NA	NA	0,40	0,11	1,51	0,1614	0,7350
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (SAP)	Region 2	Vd Arm	64	8	12,50	56	87,50	NA	NA	NA	-	-	-	-	0,7350
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (SAP)	Region 3	SVd Arm	47	5	10,64	42	89,36	NA	NA	NA	0,74	0,21	2,62	0,6419	0,7350
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (SAP)	Region 3	Vd Arm	53	6	11,32	47	88,68	NA	NA	NA	-	-	-	-	0,7350
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (SAP)	Region 4	SVd Arm	69	1	1,45	68	98,55	NA	NA	NA	0,33	0,04	3,06	0,3066	0,7350
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (SAP)	Region 4	Vd Arm	70	4	5,71	66	94,29	NA	NA	NA	-	-	-	-	0,7350
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	7	5,98	110	94,02	NA	NA	NA	0,54	0,21	1,39	0,1959	0,7730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,7730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (by medical care situation)	Rest of the world	SVd Arm	78	2	2,56	76	97,44	NA	NA	NA	0,41	0,08	2,19	0,2802	0,7730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Region (by medical care situation)	Rest of the world	Vd Arm	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,7730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	1,65	0,20	13,70	0,6389	0,2170
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Race	Races other than White	Vd Arm	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,2170
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Race	White	SVd Arm	161	7	4,35	154	95,65	NA	NA	NA	0,39	0,16	0,95	0,0328	0,2170
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Race	White	Vd Arm	162	16	9,88	146	90,12	NA	NA	NA	-	-	-	-	0,2170

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	9	5,26	162	94,74	NA	NA	NA	0,52	0,23	1,16	0,1029	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	18	9,73	167	90,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Prior PI therapies	N	SVd Arm	48	2	4,17	46	95,83	NA	NA	NA	0,39	0,08	2,04	0,2497	0,7498
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Prior PI therapies	N	Vd Arm	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,7498
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Prior PI therapies	Y	SVd Arm	147	7	4,76	140	95,24	NA	NA	NA	0,54	0,21	1,35	0,1781	0,7498
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Prior PI therapies	Y	Vd Arm	157	13	8,28	144	91,72	NA	NA	NA	-	-	-	-	0,7498
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Prior anti-MM regimen	>1	SVd Arm	98	4	4,08	94	95,92	NA	NA	NA	0,49	0,15	1,65	0,2427	0,9934
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Prior anti-MM regimen	>1	Vd Arm	104	8	7,69	96	92,31	NA	NA	NA	-	-	-	-	0,9934
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Prior anti-MM regimen	1	SVd Arm	97	5	5,15	92	94,85	NA	NA	NA	0,50	0,17	1,46	0,1946	0,9934
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Prior anti-MM regimen	1	Vd Arm	100	10	10,00	90	90,00	NA	NA	NA	-	-	-	-	0,9934
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline single cytogenetic alterations	N	SVd Arm	98	1	1,02	97	98,98	NA	NA	NA	0,08	0,01	0,66	0,0029	0,0263
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline single cytogenetic alterations	N	Vd Arm	111	12	10,81	99	89,19	NA	NA	NA	-	-	-	-	0,0263
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline single cytogenetic alterations	Y	SVd Arm	97	8	8,25	89	91,75	NA	NA	NA	1,16	0,40	3,38	0,7800	0,0263
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Baseline single cytogenetic alterations	Y	Vd Arm	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,0263
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Previously Exposed to Bortezomib	N	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	0,30	0,06	1,46	0,1157	0,4222
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Previously Exposed to Bortezomib	N	Vd Arm	62	7	11,29	55	88,71	NA	NA	NA	-	-	-	-	0,4222
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Previously Exposed to Bortezomib	Y	SVd Arm	134	7	5,22	127	94,78	NA	NA	NA	0,64	0,25	1,67	0,3621	0,4222
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger) Neuropathy Peripheral	Previously Exposed to Bortezomib	Y	Vd Arm	142	11	7,75	131	92,25	NA	NA	NA	-	-	-	-	0,4222
Patients with at least one SAESI or SAECI Thrombocytopenia	total	-	SVd Arm	195	4	2,05	191	97,95	NA	NA	NA	2,72	0,28	26,24	0,3666	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	total	-	Vd Arm	204	1	0,49	203	99,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Gender	Female	SVd Arm	80	2	2,50	78	97,50	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Thrombocytopenia	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Gender	Male	SVd Arm	115	2	1,74	113	98,26	NA	NA	NA	1,69	0,15	18,97	0,6688	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Gender	Male	Vd Arm	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Age Group	<65	SVd Arm	86	3	3,49	83	96,51	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Age Group	>=65	SVd Arm	109	1	0,92	108	99,08	NA	NA	NA	0,91	0,06	14,55	0,9465	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	4	2,31	169	97,69	NA	NA	NA	2,57	0,27	24,85	0,3982	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline ISS stage	Stage I or II	SVd Arm	163	4	2,45	159	97,55	NA	NA	NA	2,88	0,30	27,70	0,3381	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (SAP)	Region 2	SVd Arm	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (SAP)	Region 3	Vd Arm	53	1	1,89	52	98,11	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (SAP)	Region 4	SVd Arm	69	2	2,90	67	97,10	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	2	1,71	115	98,29	NA	NA	NA	1,53	0,14	16,92	0,7289	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (by medical care situation)	Rest of the world	SVd Arm	78	2	2,56	76	97,44	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Race	White	SVd Arm	161	2	1,24	159	98,76	NA	NA	NA	0,84	0,05	13,39	0,9000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Thrombocytopenia	Race	White	Vd Arm	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	2	1,17	169	98,83	NA	NA	NA	0,88	0,06	14,13	0,9305	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	1	0,54	184	99,46	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Prior PI therapies	N	SVd Arm	48	2	4,17	46	95,83	NA	NA	NA	0,82	0,05	13,17	0,8907	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Prior PI therapies	Y	SVd Arm	147	2	1,36	145	98,64	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Prior anti-MM regimen	>1	SVd Arm	98	1	1,02	97	98,98	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Prior anti-MM regimen	1	SVd Arm	97	3	3,09	94	96,91	NA	NA	NA	1,72	0,16	18,95	0,6553	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline single cytogenetic alterations	N	SVd Arm	98	2	2,04	96	97,96	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline single cytogenetic alterations	Y	SVd Arm	97	2	2,06	95	97,94	NA	NA	NA	1,59	0,14	17,50	0,7040	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Previously Exposed to Bortezomib	N	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	0,82	0,05	13,17	0,8907	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Previously Exposed to Bortezomib	Y	SVd Arm	134	2	1,49	132	98,51	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Thrombocytopenia	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	total	-	SVd Arm	195	3	1,54	192	98,46	NA	44,52	NA	2,29	0,21	25,44	0,4879	NA
Patients with at least one SAESI or SAECI Neutropenia	total	-	Vd Arm	204	1	0,49	203	99,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Gender	Female	SVd Arm	80	0	0,00	80	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Gender	Female	Vd Arm	91	1	1,10	90	98,90	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Gender	Male	SVd Arm	115	3	2,61	112	97,39	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Age Group	<65	SVd Arm	86	0	0,00	86	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neutropenia	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Neutropenia	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	NA	44,52	NA	2,07	0,19	22,81	0,5452	NA
Patients with at least one SAESI or SAECI Neutropenia	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	2	1,16	171	98,84	NA	44,52	NA	1,05	0,07	16,80	0,9742	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline ISS stage	Stage I or II	SVd Arm	163	2	1,23	161	98,77	NA	44,52	NA	1,05	0,07	16,80	0,9728	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (SAP)	Region 2	SVd Arm	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (SAP)	Region 2	Vd Arm	64	1	1,56	63	98,44	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (SAP)	Region 4	SVd Arm	69	2	2,90	67	97,10	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	1	0,85	116	99,15	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	1	0,74	135	99,26	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (by medical care situation)	Rest of the world	SVd Arm	78	2	2,56	76	97,44	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neutropenia	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Race	White	SVd Arm	161	3	1,86	158	98,14	NA	44,52	NA	2,30	0,20	26,08	0,4890	NA
Patients with at least one SAESI or SAECI Neutropenia	Race	White	Vd Arm	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neutropenia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	3	1,75	168	98,25	NA	44,52	NA	2,41	0,22	26,90	0,4612	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Neutropenia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	1	0,54	184	99,46	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neutropenia	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Prior PI therapies	Y	SVd Arm	147	3	2,04	144	97,96	NA	44,52	NA	2,29	0,21	25,44	0,4879	NA
Patients with at least one SAESI or SAECI Neutropenia	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Prior anti-MM regimen	>1	SVd Arm	98	3	3,06	95	96,94	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Prior anti-MM regimen	1	SVd Arm	97	0	0,00	97	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline single cytogenetic alterations	N	SVd Arm	98	2	2,04	96	97,96	44,52	44,52	NA	1,40	0,09	22,67	0,8104	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline single cytogenetic alterations	N	Vd Arm	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline single cytogenetic alterations	Y	SVd Arm	97	1	1,03	96	98,97	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Previously Exposed to Bortezomib	N	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neutropenia	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neutropenia	Previously Exposed to Bortezomib	Y	SVd Arm	134	3	2,24	131	97,76	NA	44,52	NA	2,45	0,22	27,39	0,4517	NA
Patients with at least one SAESI or SAECI Neutropenia	Previously Exposed to Bortezomib	Y	Vd Arm	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	total	-	SVd Arm	195	4	2,05	191	97,95	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	total	-	Vd Arm	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Gender	Female	SVd Arm	80	2	2,50	78	97,50	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Gender	Male	SVd Arm	115	2	1,74	113	98,26	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Age Group	<65	SVd Arm	86	1	1,16	85	98,84	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline R-ISS stage	Stage I or II	SVd Arm	173	3	1,73	170	98,27	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Nausea	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline ISS stage	Stage I or II	SVd Arm	163	4	2,45	159	97,55	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Nausea	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Region (SAP)	Region 2	SVd Arm	61	3	4,92	58	95,08	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Nausea	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Region (SAP)	Region 4	SVd Arm	69	0	0,00	69	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Nausea	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Region (by medical care situation)	Rest of the world	SVd Arm	78	0	0,00	78	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Nausea	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Race	White	SVd Arm	161	2	1,24	159	98,76	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Nausea	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	3	1,75	168	98,25	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Nausea	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Prior PI therapies	Y	SVd Arm	147	4	2,72	143	97,28	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Nausea	Prior anti-MM regimen	>1	SVd Arm	98	4	4,08	94	95,92	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Prior anti-MM regimen	1	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Nausea	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline single cytogenetic alterations	Y	SVd Arm	97	1	1,03	96	98,97	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Previously Exposed to Bortezomib	Y	SVd Arm	134	3	2,24	131	97,76	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Nausea	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	total	-	SVd Arm	195	7	3,59	188	96,41	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	total	-	Vd Arm	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Gender	Female	SVd Arm	80	6	7,50	74	92,50	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Gender	Male	SVd Arm	115	1	0,87	114	99,13	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Age Group	<65	SVd Arm	86	4	4,65	82	95,35	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline R-ISS stage	Stage I or II	SVd Arm	173	6	3,47	167	96,53	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline ISS stage	Stage I or II	SVd Arm	163	7	4,29	156	95,71	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Vomiting	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (SAP)	Region 2	SVd Arm	61	3	4,92	58	95,08	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Vomiting	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (SAP)	Region 4	SVd Arm	69	3	4,35	66	95,65	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (by medical care situation)	Rest of the world	SVd Arm	78	3	3,85	75	96,15	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Race	Races other than White	SVd Arm	34	5	14,71	29	85,29	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Race	White	SVd Arm	161	2	1,24	159	98,76	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Vomiting	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	5	2,92	166	97,08	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Prior PI therapies	N	SVd Arm	48	4	8,33	44	91,67	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Prior PI therapies	Y	SVd Arm	147	3	2,04	144	97,96	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Prior anti-MM regimen	>1	SVd Arm	98	4	4,08	94	95,92	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Prior anti-MM regimen	1	SVd Arm	97	3	3,09	94	96,91	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline single cytogenetic alterations	N	SVd Arm	98	4	4,08	94	95,92	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Vomiting	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline single cytogenetic alterations	Y	SVd Arm	97	3	3,09	94	96,91	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Previously Exposed to Bortezomib	N	SVd Arm	61	5	8,20	56	91,80	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Previously Exposed to Bortezomib	Y	SVd Arm	134	2	1,49	132	98,51	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Vomiting	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	total	-	SVd Arm	195	1	0,51	194	99,49	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	total	-	Vd Arm	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Gender	Female	SVd Arm	80	1	1,25	79	98,75	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Gender	Male	SVd Arm	115	0	0,00	115	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Gender	Male	Vd Arm	113	0	0,00	113	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Age Group	<65	SVd Arm	86	0	0,00	86	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Age Group	>=65	SVd Arm	109	1	0,92	108	99,08	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline R-ISS stage	Stage I or II	SVd Arm	173	1	0,58	172	99,42	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline ISS stage	Stage I or II	SVd Arm	163	1	0,61	162	99,39	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (SAP)	Region 2	SVd Arm	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Decreased Appetite	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (SAP)	Region 4	SVd Arm	69	0	0,00	69	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	1	0,85	116	99,15	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (by medical care situation)	Rest of the world	SVd Arm	78	0	0,00	78	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Race	White	SVd Arm	161	1	0,62	160	99,38	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	1	0,58	170	99,42	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Prior PI therapies	Y	SVd Arm	147	1	0,68	146	99,32	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Prior anti-MM regimen	>1	SVd Arm	98	1	1,02	97	98,98	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Prior anti-MM regimen	1	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline single cytogenetic alterations	N	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline single cytogenetic alterations	Y	SVd Arm	97	1	1,03	96	98,97	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Decreased Appetite	Previously Exposed to Bortezomib	Y	SVd Arm	134	0	0,00	134	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Decreased Appetite	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	total	-	SVd Arm	195	0	0,00	195	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	total	-	Vd Arm	204	0	0,00	204	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Gender	Female	SVd Arm	80	0	0,00	80	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Gender	Female	Vd Arm	91	0	0,00	91	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Gender	Male	SVd Arm	115	0	0,00	115	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Gender	Male	Vd Arm	113	0	0,00	113	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Age Group	<65	SVd Arm	86	0	0,00	86	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Age Group	>=65	SVd Arm	109	0	0,00	109	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline R-ISS stage	Stage I or II	SVd Arm	173	0	0,00	173	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline ISS stage	Stage I or II	SVd Arm	163	0	0,00	163	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (SAP)	Region 2	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (SAP)	Region 4	SVd Arm	69	0	0,00	69	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	0	0,00	117	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Weight Decreased	Region (by medical care situation)	Rest of the world	SVd Arm	78	0	0,00	78	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Race	White	SVd Arm	161	0	0,00	161	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Race	White	Vd Arm	162	0	0,00	162	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	0	0,00	171	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Prior PI therapies	Y	SVd Arm	147	0	0,00	147	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Prior anti-MM regimen	>1	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Prior anti-MM regimen	1	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline single cytogenetic alterations	N	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline single cytogenetic alterations	Y	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Previously Exposed to Bortezomib	N	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Weight Decreased	Previously Exposed to Bortezomib	Y	SVd Arm	134	0	0,00	134	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Weight Decreased	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Pneumonia	total	-	SVd Arm	195	29	14,87	166	85,13	NA	NA	NA	1,16	0,68	1,97	0,5881	NA
Patients with at least one SAESI or SAECI Pneumonia	total	-	Vd Arm	204	27	13,24	177	86,76	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Pneumonia	Gender	Female	SVd Arm	80	14	17,50	66	82,50	NA	34,50	NA	1,76	0,78	3,96	0,1683	0,3437

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Pneumonia	Gender	Female	Vd Arm	91	13	14,29	78	85,71	NA	NA	NA	-	-	-	-	0,3437
Patients with at least one SAESI or SAECI Pneumonia	Gender	Male	SVd Arm	115	15	13,04	100	86,96	NA	NA	NA	1,04	0,50	2,16	0,9217	0,3437
Patients with at least one SAESI or SAECI Pneumonia	Gender	Male	Vd Arm	113	14	12,39	99	87,61	NA	NA	NA	-	-	-	-	0,3437
Patients with at least one SAESI or SAECI Pneumonia	Age Group	<65	SVd Arm	86	15	17,44	71	82,56	NA	34,50	NA	1,77	0,73	4,29	0,2023	0,2362
Patients with at least one SAESI or SAECI Pneumonia	Age Group	<65	Vd Arm	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,2362
Patients with at least one SAESI or SAECI Pneumonia	Age Group	>=65	SVd Arm	109	14	12,84	95	87,16	NA	NA	NA	0,89	0,45	1,80	0,7543	0,2362
Patients with at least one SAESI or SAECI Pneumonia	Age Group	>=65	Vd Arm	129	19	14,73	110	85,27	NA	NA	NA	-	-	-	-	0,2362
Patients with at least one SAESI or SAECI Pneumonia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	27	15,61	146	84,39	NA	NA	NA	1,19	0,68	2,10	0,5458	0,7938
Patients with at least one SAESI or SAECI Pneumonia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	22	12,64	152	87,36	NA	NA	NA	-	-	-	-	0,7938
Patients with at least one SAESI or SAECI Pneumonia	Baseline R-ISS stage	Stage III	SVd Arm	12	2	16,67	10	83,33	NA	NA	NA	0,91	0,13	6,18	0,9253	0,7938
Patients with at least one SAESI or SAECI Pneumonia	Baseline R-ISS stage	Stage III	Vd Arm	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,7938
Patients with at least one SAESI or SAECI Pneumonia	Baseline ISS stage	Stage I or II	SVd Arm	163	18	11,04	145	88,96	NA	NA	NA	0,82	0,44	1,54	0,5411	0,0529
Patients with at least one SAESI or SAECI Pneumonia	Baseline ISS stage	Stage I or II	Vd Arm	173	22	12,72	151	87,28	NA	NA	NA	-	-	-	-	0,0529
Patients with at least one SAESI or SAECI Pneumonia	Baseline ISS stage	Stage III	SVd Arm	32	11	34,38	21	65,62	12,55	7,00	NA	2,82	0,96	8,29	0,0500	0,0529
Patients with at least one SAESI or SAECI Pneumonia	Baseline ISS stage	Stage III	Vd Arm	31	5	16,13	26	83,87	20,90	20,90	NA	-	-	-	-	0,0529
Patients with at least one SAESI or SAECI Pneumonia	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,7338
Patients with at least one SAESI or SAECI Pneumonia	Region (SAP)	Region 1	Vd Arm	17	2	11,76	15	88,24	-	-	-	-	-	-	-	0,7338
Patients with at least one SAESI or SAECI Pneumonia	Region (SAP)	Region 2	SVd Arm	61	9	14,75	52	85,25	34,50	34,50	NA	1,48	0,47	4,60	0,4977	0,7338
Patients with at least one SAESI or SAECI Pneumonia	Region (SAP)	Region 2	Vd Arm	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,7338
Patients with at least one SAESI or SAECI Pneumonia	Region (SAP)	Region 3	SVd Arm	47	7	14,89	40	85,11	NA	NA	NA	1,27	0,39	4,16	0,6884	0,7338
Patients with at least one SAESI or SAECI Pneumonia	Region (SAP)	Region 3	Vd Arm	53	6	11,32	47	88,68	NA	NA	NA	-	-	-	-	0,7338
Patients with at least one SAESI or SAECI Pneumonia	Region (SAP)	Region 4	SVd Arm	69	12	17,39	57	82,61	NA	NA	NA	0,89	0,41	1,92	0,7583	0,7338
Patients with at least one SAESI or SAECI Pneumonia	Region (SAP)	Region 4	Vd Arm	70	14	20,00	56	80,00	NA	NA	NA	-	-	-	-	0,7338
Patients with at least one SAESI or SAECI Pneumonia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	14	11,97	103	88,03	NA	NA	NA	1,08	0,51	2,30	0,8433	0,9023
Patients with at least one SAESI or SAECI Pneumonia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	14	10,29	122	89,71	NA	NA	NA	-	-	-	-	0,9023
Patients with at least one SAESI or SAECI Pneumonia	Region (by medical care situation)	Rest of the world	SVd Arm	78	15	19,23	63	80,77	NA	NA	NA	1,01	0,48	2,14	0,9799	0,9023
Patients with at least one SAESI or SAECI Pneumonia	Region (by medical care situation)	Rest of the world	Vd Arm	68	13	19,12	55	80,88	NA	NA	NA	-	-	-	-	0,9023
Patients with at least one SAESI or SAECI Pneumonia	Race	Races other than White	SVd Arm	34	6	17,65	28	82,35	NA	NA	NA	3,11	0,71	13,58	0,1169	0,1464
Patients with at least one SAESI or SAECI Pneumonia	Race	Races other than White	Vd Arm	42	3	7,14	39	92,86	NA	NA	NA	-	-	-	-	0,1464
Patients with at least one SAESI or SAECI Pneumonia	Race	White	SVd Arm	161	23	14,29	138	85,71	NA	NA	NA	0,96	0,54	1,72	0,8936	0,1464

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Pneumonia	Race	White	Vd Arm	162	24	14,81	138	85,19	NA	NA	NA	-	-	-	-	0,1464
Patients with at least one SAESI or SAECI Pneumonia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Pneumonia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Pneumonia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	25	14,62	146	85,38	NA	NA	NA	1,07	0,61	1,86	0,8198	NA
Patients with at least one SAESI or SAECI Pneumonia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	26	14,05	159	85,95	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Pneumonia	Prior PI therapies	N	SVd Arm	48	7	14,58	41	85,42	NA	NA	NA	1,40	0,44	4,49	0,5663	0,7145
Patients with at least one SAESI or SAECI Pneumonia	Prior PI therapies	N	Vd Arm	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,7145
Patients with at least one SAESI or SAECI Pneumonia	Prior PI therapies	Y	SVd Arm	147	22	14,97	125	85,03	NA	NA	NA	1,10	0,61	2,00	0,7550	0,7145
Patients with at least one SAESI or SAECI Pneumonia	Prior PI therapies	Y	Vd Arm	157	22	14,01	135	85,99	NA	NA	NA	-	-	-	-	0,7145
Patients with at least one SAESI or SAECI Pneumonia	Prior anti-MM regimen	>1	SVd Arm	98	17	17,35	81	82,65	NA	34,50	NA	1,49	0,72	3,08	0,2812	0,3188
Patients with at least one SAESI or SAECI Pneumonia	Prior anti-MM regimen	>1	Vd Arm	104	13	12,50	91	87,50	NA	NA	NA	-	-	-	-	0,3188
Patients with at least one SAESI or SAECI Pneumonia	Prior anti-MM regimen	1	SVd Arm	97	12	12,37	85	87,63	NA	NA	NA	0,87	0,40	1,89	0,7155	0,3188
Patients with at least one SAESI or SAECI Pneumonia	Prior anti-MM regimen	1	Vd Arm	100	14	14,00	86	86,00	NA	NA	NA	-	-	-	-	0,3188
Patients with at least one SAESI or SAECI Pneumonia	Baseline single cytogenetic alterations	N	SVd Arm	98	13	13,27	85	86,73	NA	NA	NA	1,21	0,56	2,63	0,6249	0,9256
Patients with at least one SAESI or SAECI Pneumonia	Baseline single cytogenetic alterations	N	Vd Arm	111	13	11,71	98	88,29	NA	NA	NA	-	-	-	-	0,9256
Patients with at least one SAESI or SAECI Pneumonia	Baseline single cytogenetic alterations	Y	SVd Arm	97	16	16,49	81	83,51	NA	NA	NA	1,15	0,54	2,45	0,7139	0,9256
Patients with at least one SAESI or SAECI Pneumonia	Baseline single cytogenetic alterations	Y	Vd Arm	93	14	15,05	79	84,95	NA	NA	NA	-	-	-	-	0,9256
Patients with at least one SAESI or SAECI Pneumonia	Previously Exposed to Bortezomib	N	SVd Arm	61	9	14,75	52	85,25	NA	34,50	NA	1,40	0,44	4,49	0,5663	0,6063
Patients with at least one SAESI or SAECI Pneumonia	Previously Exposed to Bortezomib	N	Vd Arm	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,6063
Patients with at least one SAESI or SAECI Pneumonia	Previously Exposed to Bortezomib	Y	SVd Arm	134	20	14,93	114	85,07	NA	NA	NA	0,99	0,54	1,83	0,9828	0,6063
Patients with at least one SAESI or SAECI Pneumonia	Previously Exposed to Bortezomib	Y	Vd Arm	142	22	15,49	120	84,51	NA	NA	NA	-	-	-	-	0,6063
Patients with at least one SAESI or SAECI Sepsis	total	-	SVd Arm	195	8	4,10	187	95,90	NA	NA	NA	4,14	0,87	19,68	0,0530	NA
Patients with at least one SAESI or SAECI Sepsis	total	-	Vd Arm	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Gender	Female	SVd Arm	80	6	7,50	74	92,50	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Gender	Female	Vd Arm	91	1	1,10	90	98,90	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Gender	Male	SVd Arm	115	2	1,74	113	98,26	NA	NA	NA	2,09	0,19	23,10	0,5383	NA
Patients with at least one SAESI or SAECI Sepsis	Gender	Male	Vd Arm	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Age Group	<65	SVd Arm	86	4	4,65	82	95,35	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Sepsis	Age Group	>=65	SVd Arm	109	4	3,67	105	96,33	NA	NA	NA	2,50	0,44	14,10	0,2832	NA
Patients with at least one SAESI or SAECI Sepsis	Age Group	>=65	Vd Arm	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Baseline R-ISS stage	Stage I or II	SVd Arm	173	7	4,05	166	95,95	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	NA	NA	NA	1,22	0,06	25,98	0,8964	NA
Patients with at least one SAESI or SAECI Sepsis	Baseline R-ISS stage	Stage III	Vd Arm	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Baseline ISS stage	Stage I or II	SVd Arm	163	6	3,68	157	96,32	NA	NA	NA	6,03	0,72	50,10	0,0582	0,5331
Patients with at least one SAESI or SAECI Sepsis	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	0,5331
Patients with at least one SAESI or SAECI Sepsis	Baseline ISS stage	Stage III	SVd Arm	32	2	6,25	30	93,75	NA	NA	NA	2,17	0,20	24,15	0,5174	0,5331
Patients with at least one SAESI or SAECI Sepsis	Baseline ISS stage	Stage III	Vd Arm	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,5331
Patients with at least one SAESI or SAECI Sepsis	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Sepsis	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Region (SAP)	Region 2	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	0,89	0,12	6,51	0,9099	NA
Patients with at least one SAESI or SAECI Sepsis	Region (SAP)	Region 2	Vd Arm	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Region (SAP)	Region 3	SVd Arm	47	1	2,13	46	97,87	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Region (SAP)	Region 4	SVd Arm	69	5	7,25	64	92,75	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	3	2,56	114	97,44	NA	NA	NA	1,83	0,30	11,22	0,5058	NA
Patients with at least one SAESI or SAECI Sepsis	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Region (by medical care situation)	Rest of the world	SVd Arm	78	5	6,41	73	93,59	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Race	Races other than White	SVd Arm	34	5	14,71	29	85,29	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Race	White	SVd Arm	161	3	1,86	158	98,14	NA	NA	NA	1,66	0,26	10,38	0,5856	NA
Patients with at least one SAESI or SAECI Sepsis	Race	White	Vd Arm	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Sepsis	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	7	4,09	164	95,91	NA	NA	NA	4,11	0,82	20,69	0,0661	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Sepsis	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	NA	NA	NA	1,31	0,08	22,28	0,8518	0,3637
Patients with at least one SAESI or SAECI Sepsis	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,3637
Patients with at least one SAESI or SAECI Sepsis	Prior PI therapies	Y	SVd Arm	147	7	4,76	140	95,24	NA	NA	NA	6,71	0,82	54,57	0,0394	0,3637
Patients with at least one SAESI or SAECI Sepsis	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,3637
Patients with at least one SAESI or SAECI Sepsis	Prior anti-MM regimen	>1	SVd Arm	98	7	7,14	91	92,86	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Prior anti-MM regimen	1	SVd Arm	97	1	1,03	96	98,97	NA	NA	NA	0,64	0,06	7,19	0,7123	NA
Patients with at least one SAESI or SAECI Sepsis	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Baseline single cytogenetic alterations	N	SVd Arm	98	6	6,12	92	93,88	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Baseline single cytogenetic alterations	Y	SVd Arm	97	2	2,06	95	97,94	NA	NA	NA	1,50	0,13	16,79	0,7390	NA
Patients with at least one SAESI or SAECI Sepsis	Baseline single cytogenetic alterations	Y	Vd Arm	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	NA	NA	NA	0,89	0,07	10,91	0,9280	NA
Patients with at least one SAESI or SAECI Sepsis	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Previously Exposed to Bortezomib	Y	SVd Arm	134	7	5,22	127	94,78	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Sepsis	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	total	-	SVd Arm	195	3	1,54	192	98,46	NA	NA	NA	1,71	0,28	10,44	0,5547	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	total	-	Vd Arm	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Gender	Female	SVd Arm	80	2	2,50	78	97,50	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Gender	Male	SVd Arm	115	1	0,87	114	99,13	NA	NA	NA	0,59	0,05	6,91	0,6724	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Gender	Male	Vd Arm	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Age Group	<65	SVd Arm	86	1	1,16	85	98,84	NA	NA	NA	0,25	0,02	2,82	0,2256	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Age Group	<65	Vd Arm	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Age Group	>=65	SVd Arm	109	2	1,83	107	98,17	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline R-ISS stage	Stage I or II	SVd Arm	173	3	1,73	170	98,27	NA	NA	NA	1,45	0,24	8,75	0,6831	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline R-ISS stage	Stage I or II	Vd Arm	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline ISS stage	Stage I or II	SVd Arm	163	3	1,84	160	98,16	NA	NA	NA	1,62	0,27	9,68	0,5951	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline ISS stage	Stage I or II	Vd Arm	173	2	1,16	171	98,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (SAP)	Region 2	SVd Arm	61	2	3,28	59	96,72	NA	25,23	NA	2,68	0,22	33,12	0,4297	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (SAP)	Region 2	Vd Arm	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (SAP)	Region 4	SVd Arm	69	1	1,45	68	98,55	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	2	1,71	115	98,29	NA	NA	NA	1,32	0,17	10,01	0,7891	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (by medical care situation)	Rest of the world	SVd Arm	78	1	1,28	77	98,72	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Race	Races other than White	SVd Arm	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Race	White	SVd Arm	161	2	1,24	159	98,76	NA	NA	NA	1,19	0,16	9,02	0,8644	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Race	White	Vd Arm	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	2	1,17	169	98,83	NA	NA	NA	1,09	0,15	7,76	0,9313	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	NA	NA	NA	0,92	0,06	14,79	0,9524	0,5743
Patients with at least one SAESI or SAECI Opportunistic Infection	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,5743
Patients with at least one SAESI or SAECI Opportunistic Infection	Prior PI therapies	Y	SVd Arm	147	2	1,36	145	98,64	NA	NA	NA	2,64	0,23	29,71	0,4143	0,5743
Patients with at least one SAESI or SAECI Opportunistic Infection	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,5743

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Opportunistic Infection	Prior anti-MM regimen	>1	SVd Arm	98	2	2,04	96	97,96	NA	NA	NA	2,07	0,19	23,04	0,5459	0,8102
Patients with at least one SAESI or SAECI Opportunistic Infection	Prior anti-MM regimen	>1	Vd Arm	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	0,8102
Patients with at least one SAESI or SAECI Opportunistic Infection	Prior anti-MM regimen	1	SVd Arm	97	1	1,03	96	98,97	NA	NA	NA	1,31	0,08	21,84	0,8484	0,8102
Patients with at least one SAESI or SAECI Opportunistic Infection	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,8102
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	4,60	0,43	49,42	0,1772	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline single cytogenetic alterations	N	Vd Arm	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline single cytogenetic alterations	Y	SVd Arm	97	0	0,00	97	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Opportunistic Infection	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	NA	NA	NA	0,92	0,06	14,79	0,9524	0,5476
Patients with at least one SAESI or SAECI Opportunistic Infection	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,5476
Patients with at least one SAESI or SAECI Opportunistic Infection	Previously Exposed to Bortezomib	Y	SVd Arm	134	2	1,49	132	98,51	NA	NA	NA	2,85	0,25	32,12	0,3771	0,5476
Patients with at least one SAESI or SAECI Opportunistic Infection	Previously Exposed to Bortezomib	Y	Vd Arm	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	0,5476
Patients with at least one SAESI or SAECI Blurred Vision	total	-	SVd Arm	195	0	0,00	195	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	total	-	Vd Arm	204	0	0,00	204	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Gender	Female	SVd Arm	80	0	0,00	80	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Gender	Female	Vd Arm	91	0	0,00	91	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Gender	Male	SVd Arm	115	0	0,00	115	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Gender	Male	Vd Arm	113	0	0,00	113	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Age Group	<65	SVd Arm	86	0	0,00	86	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Age Group	>=65	SVd Arm	109	0	0,00	109	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline R-ISS stage	Stage I or II	SVd Arm	173	0	0,00	173	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline ISS stage	Stage I or II	SVd Arm	163	0	0,00	163	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Blurred Vision	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (SAP)	Region 2	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (SAP)	Region 4	SVd Arm	69	0	0,00	69	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	0	0,00	117	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (by medical care situation)	Rest of the world	SVd Arm	78	0	0,00	78	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Race	White	SVd Arm	161	0	0,00	161	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Race	White	Vd Arm	162	0	0,00	162	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	0	0,00	171	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Prior PI therapies	Y	SVd Arm	147	0	0,00	147	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Prior anti-MM regimen	>1	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Prior anti-MM regimen	1	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline single cytogenetic alterations	N	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Blurred Vision	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline single cytogenetic alterations	Y	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Previously Exposed to Bortezomib	N	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Blurred Vision	Previously Exposed to Bortezomib	Y	SVd Arm	134	0	0,00	134	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Blurred Vision	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	total	-	SVd Arm	195	9	4,62	186	95,38	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	total	-	Vd Arm	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Gender	Female	SVd Arm	80	5	6,25	75	93,75	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Gender	Male	SVd Arm	115	4	3,48	111	96,52	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Age Group	<65	SVd Arm	86	6	6,98	80	93,02	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline R-ISS stage	Stage I or II	SVd Arm	173	8	4,62	165	95,38	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Cataract	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline ISS stage	Stage I or II	SVd Arm	163	8	4,91	155	95,09	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	NA	27,14	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Cataract	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	NA	32,00	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Cataract	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (SAP)	Region 2	SVd Arm	61	4	6,56	57	93,44	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Cataract	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (SAP)	Region 4	SVd Arm	69	4	5,80	65	94,20	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (by medical care situation)	Rest of the world	SVd Arm	78	5	6,41	73	93,59	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Race	Races other than White	SVd Arm	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Race	White	SVd Arm	161	8	4,97	153	95,03	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Cataract	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	8	4,68	163	95,32	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Prior PI therapies	N	SVd Arm	48	3	6,25	45	93,75	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Prior PI therapies	Y	SVd Arm	147	6	4,08	141	95,92	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Prior anti-MM regimen	>1	SVd Arm	98	5	5,10	93	94,90	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Prior anti-MM regimen	1	SVd Arm	97	4	4,12	93	95,88	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline single cytogenetic alterations	N	SVd Arm	98	4	4,08	94	95,92	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline single cytogenetic alterations	Y	SVd Arm	97	5	5,15	92	94,85	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Previously Exposed to Bortezomib	N	SVd Arm	61	4	6,56	57	93,44	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Cataract	Previously Exposed to Bortezomib	Y	SVd Arm	134	5	3,73	129	96,27	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cataract	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	total	-	SVd Arm	195	1	0,51	194	99,49	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	total	-	Vd Arm	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Gender	Female	SVd Arm	80	1	1,25	79	98,75	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Gender	Male	SVd Arm	115	0	0,00	115	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Gender	Male	Vd Arm	113	0	0,00	113	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Age Group	<65	SVd Arm	86	1	1,16	85	98,84	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Age Group	>=65	SVd Arm	109	0	0,00	109	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline R-ISS stage	Stage I or II	SVd Arm	173	1	0,58	172	99,42	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline R-ISS stage	Stage I or II	Vd Arm	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline ISS stage	Stage I or II	SVd Arm	163	1	0,61	162	99,39	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline ISS stage	Stage I or II	Vd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (SAP)	Region 2	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (SAP)	Region 4	SVd Arm	69	1	1,45	68	98,55	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	0	0,00	117	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Hyponatraemia	Region (by medical care situation)	Rest of the world	SVd Arm	78	1	1,28	77	98,72	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Race	White	SVd Arm	161	1	0,62	160	99,38	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	1	0,58	170	99,42	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Prior PI therapies	Y	SVd Arm	147	1	0,68	146	99,32	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Prior anti-MM regimen	>1	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Prior anti-MM regimen	1	SVd Arm	97	1	1,03	96	98,97	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline single cytogenetic alterations	N	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline single cytogenetic alterations	Y	SVd Arm	97	1	1,03	96	98,97	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Previously Exposed to Bortezomib	N	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Previously Exposed to Bortezomib	Y	SVd Arm	134	1	0,75	133	99,25	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hyponatraemia	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	total	-	SVd Arm	195	3	1,54	192	98,46	NA	NA	NA	2,20	0,20	24,41	0,5088	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	total	-	Vd Arm	204	1	0,49	203	99,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Gender	Female	SVd Arm	80	1	1,25	79	98,75	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Neurological Toxicity	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Gender	Male	SVd Arm	115	2	1,74	113	98,26	NA	NA	NA	0,84	0,05	13,36	0,8987	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Gender	Male	Vd Arm	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Age Group	<65	SVd Arm	86	0	0,00	86	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	NA	NA	NA	2,79	0,25	31,21	0,3845	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline R-ISS stage	Stage I or II	SVd Arm	173	3	1,73	170	98,27	NA	NA	NA	3,26	0,34	31,38	0,2782	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline R-ISS stage	Stage I or II	Vd Arm	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline ISS stage	Stage I or II	SVd Arm	163	3	1,84	160	98,16	NA	NA	NA	3,30	0,34	31,69	0,2736	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (SAP)	Region 2	SVd Arm	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (SAP)	Region 4	SVd Arm	69	2	2,90	67	97,10	NA	NA	NA	0,98	0,06	15,78	0,9912	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (SAP)	Region 4	Vd Arm	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	1	0,85	116	99,15	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (by medical care situation)	Rest of the world	SVd Arm	78	2	2,56	76	97,44	NA	NA	NA	0,92	0,06	14,74	0,9529	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Region (by medical care situation)	Rest of the world	Vd Arm	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Race	Races other than White	SVd Arm	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Race	White	SVd Arm	161	2	1,24	159	98,76	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Neurological Toxicity	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	2	1,17	169	98,83	NA	NA	NA	1,24	0,08	19,91	0,8809	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	1	0,54	184	99,46	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Prior PI therapies	Y	SVd Arm	147	3	2,04	144	97,96	NA	NA	NA	2,20	0,20	24,41	0,5088	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Prior anti-MM regimen	>1	SVd Arm	98	2	2,04	96	97,96	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Prior anti-MM regimen	1	SVd Arm	97	1	1,03	96	98,97	NA	NA	NA	1,01	0,06	16,08	0,9969	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	2,35	0,21	26,08	0,4732	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline single cytogenetic alterations	N	Vd Arm	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline single cytogenetic alterations	Y	SVd Arm	97	0	0,00	97	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Previously Exposed to Bortezomib	N	SVd Arm	61	1	1,64	60	98,36	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Previously Exposed to Bortezomib	Y	SVd Arm	134	2	1,49	132	98,51	NA	NA	NA	0,96	0,06	15,36	0,9775	NA
Patients with at least one SAESI or SAECI Neurological Toxicity	Previously Exposed to Bortezomib	Y	Vd Arm	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	total	-	SVd Arm	195	1	0,51	194	99,49	NA	NA	NA	1,23	0,08	19,75	0,8846	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	total	-	Vd Arm	204	1	0,49	203	99,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Gender	Female	SVd Arm	80	1	1,25	79	98,75	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Gender	Female	Vd Arm	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Gender	Male	SVd Arm	115	0	0,00	115	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Gender	Male	Vd Arm	113	1	0,88	112	99,12	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Age Group	<65	SVd Arm	86	0	0,00	86	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Age Group	<65	Vd Arm	75	1	1,33	74	98,67	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Age Group	>=65	SVd Arm	109	1	0,92	108	99,08	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Age Group	>=65	Vd Arm	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline R-ISS stage	Stage I or II	SVd Arm	173	1	0,58	172	99,42	NA	NA	NA	1,03	0,06	16,44	0,9845	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline R-ISS stage	Stage I or II	Vd Arm	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline ISS stage	Stage I or II	SVd Arm	163	1	0,61	162	99,39	NA	NA	NA	0,94	0,06	15,13	0,9672	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (SAP)	Region 2	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (SAP)	Region 3	SVd Arm	47	1	2,13	46	97,87	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (SAP)	Region 4	SVd Arm	69	0	0,00	69	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (SAP)	Region 4	Vd Arm	70	1	1,43	69	98,57	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	1	0,85	116	99,15	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (by medical care situation)	Rest of the world	SVd Arm	78	0	0,00	78	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Region (by medical care situation)	Rest of the world	Vd Arm	68	1	1,47	67	98,53	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Race	White	SVd Arm	161	1	0,62	160	99,38	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Race	White	Vd Arm	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	1	0,58	170	99,42	NA	NA	NA	1,29	0,08	20,94	0,8555	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	1	0,54	184	99,46	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Prior PI therapies	N	Vd Arm	47	0	0,00	47	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Prior PI therapies	Y	SVd Arm	147	1	0,68	146	99,32	NA	NA	NA	1,23	0,08	19,75	0,8846	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Prior anti-MM regimen	>1	SVd Arm	98	1	1,02	97	98,98	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Prior anti-MM regimen	1	SVd Arm	97	0	0,00	97	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline single cytogenetic alterations	N	SVd Arm	98	0	0,00	98	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline single cytogenetic alterations	Y	SVd Arm	97	1	1,03	96	98,97	NA	NA	NA	0,71	0,04	11,36	0,8058	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Previously Exposed to Bortezomib	N	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Previously Exposed to Bortezomib	N	Vd Arm	62	0	0,00	62	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Previously Exposed to Bortezomib	Y	SVd Arm	134	1	0,75	133	99,25	NA	NA	NA	1,29	0,08	20,57	0,8583	NA
Patients with at least one SAESI or SAECI Hepatobiliary Disorders	Previously Exposed to Bortezomib	Y	Vd Arm	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	total	-	SVd Arm	195	5	2,56	190	97,44	NA	NA	NA	2,18	0,42	11,36	0,3436	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	total	-	Vd Arm	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Gender	Female	SVd Arm	80	2	2,50	78	97,50	NA	NA	NA	1,30	0,17	9,64	0,7997	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Gender	Female	Vd Arm	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Gender	Male	SVd Arm	115	3	2,61	112	97,39	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Age Group	<65	SVd Arm	86	1	1,16	85	98,84	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Age Group	>=65	SVd Arm	109	4	3,67	105	96,33	NA	NA	NA	2,17	0,38	12,44	0,3749	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Age Group	>=65	Vd Arm	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline R-ISS stage	Stage I or II	SVd Arm	173	5	2,89	168	97,11	NA	NA	NA	2,06	0,39	10,77	0,3840	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline R-ISS stage	Stage I or II	Vd Arm	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline ISS stage	Stage I or II	SVd Arm	163	5	3,07	158	96,93	NA	NA	NA	2,32	0,44	12,08	0,3048	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline ISS stage	Stage I or II	Vd Arm	173	2	1,16	171	98,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,8081
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	0,8081
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (SAP)	Region 2	SVd Arm	61	2	3,28	59	96,72	-	-	-	-	-	-	-	0,8081
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	0,8081
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (SAP)	Region 3	SVd Arm	47	2	4,26	45	95,74	NA	NA	NA	1,43	0,11	18,51	0,7813	0,8081
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (SAP)	Region 3	Vd Arm	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,8081
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (SAP)	Region 4	SVd Arm	69	1	1,45	68	98,55	NA	NA	NA	0,89	0,05	15,11	0,9383	0,8081
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (SAP)	Region 4	Vd Arm	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,8081
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	NA	NA	NA	3,69	0,40	33,82	0,2174	0,5055
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,5055
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (by medical care situation)	Rest of the world	SVd Arm	78	1	1,28	77	98,72	NA	NA	NA	1,10	0,07	18,12	0,9492	0,5055
Patients with at least one SAESI or SAECI Cardiac Toxicity	Region (by medical care situation)	Rest of the world	Vd Arm	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,5055
Patients with at least one SAESI or SAECI Cardiac Toxicity	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Race	White	SVd Arm	161	5	3,11	156	96,89	NA	NA	NA	2,17	0,41	11,53	0,3538	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Race	White	Vd Arm	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	5	2,92	166	97,08	NA	NA	NA	2,33	0,45	12,14	0,3007	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Prior PI therapies	N	SVd Arm	48	2	4,17	46	95,83	NA	NA	NA	1,49	0,13	16,99	0,7489	0,6923
Patients with at least one SAESI or SAECI Cardiac Toxicity	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,6923
Patients with at least one SAESI or SAECI Cardiac Toxicity	Prior PI therapies	Y	SVd Arm	147	3	2,04	144	97,96	NA	NA	NA	2,91	0,30	27,98	0,3329	0,6923
Patients with at least one SAESI or SAECI Cardiac Toxicity	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,6923

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Cardiac Toxicity	Prior anti-MM regimen	>1	SVd Arm	98	2	2,04	96	97,96	NA	NA	NA	0,98	0,14	6,97	0,9844	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Prior anti-MM regimen	>1	Vd Arm	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Prior anti-MM regimen	1	SVd Arm	97	3	3,09	94	96,91	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Prior anti-MM regimen	1	Vd Arm	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	2,41	0,24	24,26	0,4418	0,8539
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline single cytogenetic alterations	N	Vd Arm	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	0,8539
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline single cytogenetic alterations	Y	SVd Arm	97	2	2,06	95	97,94	NA	NA	NA	1,76	0,15	20,38	0,6481	0,8539
Patients with at least one SAESI or SAECI Cardiac Toxicity	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,8539
Patients with at least one SAESI or SAECI Cardiac Toxicity	Previously Exposed to Bortezomib	N	SVd Arm	61	4	6,56	57	93,44	NA	NA	NA	0,82	0,11	6,08	0,8495	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Previously Exposed to Bortezomib	Y	SVd Arm	134	1	0,75	133	99,25	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Cardiac Toxicity	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
~~Patients with at least one SAESI or SAECI Fatigue~~	~~total~~	-	~~SVd Arm~~	~~195~~	~~4~~	~~2,05~~	~~191~~	~~97,95~~	~~NA~~	~~NA~~	~~NA~~	~~1,61~~	~~0,35~~	~~7,35~~	~~0,5321~~	~~NA~~
~~Patients with at least one SAESI or SAECI Fatigue~~	~~total~~	-	~~Vd Arm~~	~~204~~	~~3~~	~~1,47~~	~~201~~	~~98,53~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	~~NA~~
Patients with at least one SAESI or SAECI Fatigue	Gender	Female	SVd Arm	80	0	0,00	80	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Gender	Female	Vd Arm	91	1	1,10	90	98,90	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Gender	Male	SVd Arm	115	4	3,48	111	96,52	NA	NA	NA	1,94	0,35	10,69	0,4401	NA
Patients with at least one SAESI or SAECI Fatigue	Gender	Male	Vd Arm	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Age Group	<65	SVd Arm	86	1	1,16	85	98,84	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Age Group	>=65	SVd Arm	109	3	2,75	106	97,25	NA	NA	NA	1,25	0,25	6,33	0,7885	NA
Patients with at least one SAESI or SAECI Fatigue	Age Group	>=65	Vd Arm	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline R-ISS stage	Stage I or II	SVd Arm	173	4	2,31	169	97,69	NA	NA	NA	1,90	0,35	10,44	0,4514	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline R-ISS stage	Stage I or II	Vd Arm	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline ISS stage	Stage I or II	SVd Arm	163	3	1,84	160	98,16	NA	NA	NA	1,05	0,21	5,21	0,9535	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline ISS stage	Stage I or II	Vd Arm	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline ISS stage	Stage III	SVd Arm	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Fatigue	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Fatigue	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Region (SAP)	Region 2	SVd Arm	61	1	1,64	60	98,36	NA	NA	NA	0,44	0,04	4,37	0,4725	NA
Patients with at least one SAESI or SAECI Fatigue	Region (SAP)	Region 2	Vd Arm	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Region (SAP)	Region 3	SVd Arm	47	1	2,13	46	97,87	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Region (SAP)	Region 4	SVd Arm	69	2	2,90	67	97,10	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	1	0,85	116	99,15	NA	NA	NA	0,51	0,04	6,26	0,5950	0,3104
Patients with at least one SAESI or SAECI Fatigue	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	0,3104
Patients with at least one SAESI or SAECI Fatigue	Region (by medical care situation)	Rest of the world	SVd Arm	78	3	3,85	75	96,15	NA	NA	NA	2,94	0,30	28,53	0,3286	0,3104
Patients with at least one SAESI or SAECI Fatigue	Region (by medical care situation)	Rest of the world	Vd Arm	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,3104
Patients with at least one SAESI or SAECI Fatigue	Race	Races other than White	SVd Arm	34	2	5,88	32	94,12	NA	NA	NA	1,37	0,12	15,18	0,7961	0,9258
Patients with at least one SAESI or SAECI Fatigue	Race	Races other than White	Vd Arm	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,9258
Patients with at least one SAESI or SAECI Fatigue	Race	White	SVd Arm	161	2	1,24	159	98,76	NA	NA	NA	1,18	0,16	8,83	0,8709	0,9258
Patients with at least one SAESI or SAECI Fatigue	Race	White	Vd Arm	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	0,9258
Patients with at least one SAESI or SAECI Fatigue	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Fatigue	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	4	2,34	167	97,66	NA	NA	NA	1,72	0,38	7,85	0,4777	NA
Patients with at least one SAESI or SAECI Fatigue	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	3	1,62	182	98,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Prior PI therapies	N	SVd Arm	48	1	2,08	47	97,92	NA	NA	NA	0,50	0,04	5,49	0,5597	0,2025
Patients with at least one SAESI or SAECI Fatigue	Prior PI therapies	N	Vd Arm	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,2025
Patients with at least one SAESI or SAECI Fatigue	Prior PI therapies	Y	SVd Arm	147	3	2,04	144	97,96	NA	NA	NA	4,29	0,44	42,28	0,1761	0,2025
Patients with at least one SAESI or SAECI Fatigue	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,2025
Patients with at least one SAESI or SAECI Fatigue	Prior anti-MM regimen	>1	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	3,96	0,40	38,94	0,2051	0,2423
Patients with at least one SAESI or SAECI Fatigue	Prior anti-MM regimen	>1	Vd Arm	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	0,2423
Patients with at least one SAESI or SAECI Fatigue	Prior anti-MM regimen	1	SVd Arm	97	1	1,03	96	98,97	NA	NA	NA	0,54	0,05	6,11	0,6151	0,2423
Patients with at least one SAESI or SAECI Fatigue	Prior anti-MM regimen	1	Vd Arm	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,2423
Patients with at least one SAESI or SAECI Fatigue	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	NA	NA	NA	1,39	0,27	7,15	0,6894	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Fatigue	Baseline single cytogenetic alterations	N	Vd Arm	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline single cytogenetic alterations	Y	SVd Arm	97	1	1,03	96	98,97	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Baseline single cytogenetic alterations	Y	Vd Arm	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Fatigue	Previously Exposed to Bortezomib	N	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	1,10	0,15	7,91	0,9231	0,4620
Patients with at least one SAESI or SAECI Fatigue	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,4620
Patients with at least one SAESI or SAECI Fatigue	Previously Exposed to Bortezomib	Y	SVd Arm	134	2	1,49	132	98,51	NA	NA	NA	3,56	0,31	40,49	0,2755	0,4620
Patients with at least one SAESI or SAECI Fatigue	Previously Exposed to Bortezomib	Y	Vd Arm	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	0,4620
~~Patients with at least one SAESI or SAECI Haemorrhages~~	~~total~~	-	~~SVd Arm~~	~~195~~	~~8~~	~~4,10~~	~~187~~	~~95,90~~	~~NA~~	~~NA~~	~~NA~~	~~7,84~~	~~0,98~~	~~62,84~~	~~0,0215~~	~~NA~~
~~Patients with at least one SAESI or SAECI Haemorrhages~~	~~total~~	-	~~Vd Arm~~	~~204~~	~~1~~	~~0,49~~	~~203~~	~~99,51~~	~~NA~~	~~NA~~	~~NA~~	-	-	-	-	~~NA~~
Patients with at least one SAESI or SAECI Haemorrhages	Gender	Female	SVd Arm	80	1	1,25	79	98,75	NA	NA	NA	0,85	0,05	14,12	0,9121	NA
Patients with at least one SAESI or SAECI Haemorrhages	Gender	Female	Vd Arm	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Gender	Male	SVd Arm	115	7	6,09	108	93,91	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Gender	Male	Vd Arm	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Age Group	<65	SVd Arm	86	2	2,33	84	97,67	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Age Group	<65	Vd Arm	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Age Group	>=65	SVd Arm	109	6	5,50	103	94,50	NA	NA	NA	7,11	0,85	59,55	0,0357	NA
Patients with at least one SAESI or SAECI Haemorrhages	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline R-ISS stage	Stage I or II	SVd Arm	173	7	4,05	166	95,95	NA	NA	NA	6,34	0,77	51,89	0,0491	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline R-ISS stage	Stage I or II	Vd Arm	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline R-ISS stage	Stage III	SVd Arm	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline ISS stage	Stage I or II	SVd Arm	163	5	3,07	158	96,93	NA	NA	NA	4,89	0,57	42,06	0,1095	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline ISS stage	Stage I or II	Vd Arm	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline ISS stage	Stage III	SVd Arm	32	3	9,38	29	90,62	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (SAP)	Region 1	SVd Arm	18	1	5,56	17	94,44	NA	NA	NA	0,50	0,03	8,46	0,6250	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (SAP)	Region 1	Vd Arm	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (SAP)	Region 2	SVd Arm	61	4	6,56	57	93,44	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Haemorrhages	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (SAP)	Region 4	SVd Arm	69	3	4,35	66	95,65	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (SAP)	Region 4	Vd Arm	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	4	3,42	113	96,58	NA	NA	NA	4,05	0,45	36,66	0,1786	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (by medical care situation)	Rest of the world	SVd Arm	78	4	5,13	74	94,87	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Region (by medical care situation)	Rest of the world	Vd Arm	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Race	Races other than White	SVd Arm	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Race	White	SVd Arm	161	7	4,35	154	95,65	NA	NA	NA	6,51	0,80	53,15	0,0446	NA
Patients with at least one SAESI or SAECI Haemorrhages	Race	White	Vd Arm	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Haemorrhages	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	7	4,09	164	95,91	NA	NA	NA	7,23	0,89	58,95	0,0306	NA
Patients with at least one SAESI or SAECI Haemorrhages	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	1	0,54	184	99,46	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Prior PI therapies	N	SVd Arm	48	2	4,17	46	95,83	NA	NA	NA	1,80	0,16	19,90	0,6277	NA
Patients with at least one SAESI or SAECI Haemorrhages	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Prior PI therapies	Y	SVd Arm	147	6	4,08	141	95,92	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Prior PI therapies	Y	Vd Arm	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Prior anti-MM regimen	>1	SVd Arm	98	3	3,06	95	96,94	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Prior anti-MM regimen	>1	Vd Arm	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Prior anti-MM regimen	1	SVd Arm	97	5	5,15	92	94,85	NA	NA	NA	4,81	0,56	41,29	0,1141	NA
Patients with at least one SAESI or SAECI Haemorrhages	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline single cytogenetic alterations	N	SVd Arm	98	3	3,06	95	96,94	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline single cytogenetic alterations	N	Vd Arm	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline single cytogenetic alterations	Y	SVd Arm	97	5	5,15	92	94,85	NA	NA	NA	3,52	0,41	30,48	0,2229	NA
Patients with at least one SAESI or SAECI Haemorrhages	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Previously Exposed to Bortezomib	N	SVd Arm	61	2	3,28	59	96,72	NA	NA	NA	1,80	0,16	19,90	0,6277	NA
Patients with at least one SAESI or SAECI Haemorrhages	Previously Exposed to Bortezomib	N	Vd Arm	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Haemorrhages	Previously Exposed to Bortezomib	Y	SVd Arm	134	6	4,48	128	95,52	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Haemorrhages	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
~~Patients with at least one SAESI or SAECI Neuropathy Peripheral~~	~~total~~	-	~~SVd Arm~~	~~195~~	~~0~~	~~0,00~~	~~195~~	~~100,00~~	-	-	-	-	-	-	-	~~NA~~
~~Patients with at least one SAESI or SAECI Neuropathy Peripheral~~	~~total~~	-	~~Vd Arm~~	~~204~~	~~2~~	~~0,98~~	~~202~~	~~99,02~~	-	-	-	-	-	-	-	~~NA~~
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Gender	Female	SVd Arm	80	0	0,00	80	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Gender	Female	Vd Arm	91	0	0,00	91	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Gender	Male	SVd Arm	115	0	0,00	115	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Gender	Male	Vd Arm	113	2	1,77	111	98,23	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Age Group	<65	SVd Arm	86	0	0,00	86	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Age Group	<65	Vd Arm	75	1	1,33	74	98,67	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Age Group	>=65	SVd Arm	109	0	0,00	109	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Age Group	>=65	Vd Arm	129	1	0,78	128	99,22	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline R-ISS stage	Stage I or II	SVd Arm	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline R-ISS stage	Stage I or II	Vd Arm	174	2	1,15	172	98,85	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline R-ISS stage	Stage III	SVd Arm	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline R-ISS stage	Stage III	Vd Arm	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline ISS stage	Stage I or II	SVd Arm	163	0	0,00	163	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline ISS stage	Stage I or II	Vd Arm	173	2	1,16	171	98,84	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline ISS stage	Stage III	SVd Arm	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline ISS stage	Stage III	Vd Arm	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (SAP)	Region 1	SVd Arm	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (SAP)	Region 1	Vd Arm	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (SAP)	Region 2	SVd Arm	61	0	0,00	61	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (SAP)	Region 2	Vd Arm	64	0	0,00	64	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (SAP)	Region 3	SVd Arm	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (SAP)	Region 3	Vd Arm	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (SAP)	Region 4	SVd Arm	69	0	0,00	69	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (SAP)	Region 4	Vd Arm	70	2	2,86	68	97,14	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	117	0	0,00	117	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	136	0	0,00	136	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (by medical care situation)	Rest of the world	SVd Arm	78	0	0,00	78	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Region (by medical care situation)	Rest of the world	Vd Arm	68	2	2,94	66	97,06	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Race	Races other than White	SVd Arm	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Race	Races other than White	Vd Arm	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Race	White	SVd Arm	161	0	0,00	161	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Race	White	Vd Arm	162	2	1,23	160	98,77	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Ethnicity	HISPANIC OR LATINO	SVd Arm	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Ethnicity	HISPANIC OR LATINO	Vd Arm	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	171	0	0,00	171	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	185	2	1,08	183	98,92	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Prior PI therapies	N	SVd Arm	48	0	0,00	48	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Prior PI therapies	N	Vd Arm	47	1	2,13	46	97,87	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Prior PI therapies	Y	SVd Arm	147	0	0,00	147	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Prior PI therapies	Y	Vd Arm	157	1	0,64	156	99,36	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Prior anti-MM regimen	>1	SVd Arm	98	0	0,00	98	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Prior anti-MM regimen	>1	Vd Arm	104	1	0,96	103	99,04	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Prior anti-MM regimen	1	SVd Arm	97	0	0,00	97	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Prior anti-MM regimen	1	Vd Arm	100	1	1,00	99	99,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline single cytogenetic alterations	N	SVd Arm	98	0	0,00	98	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline single cytogenetic alterations	N	Vd Arm	111	1	0,90	110	99,10	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline single cytogenetic alterations	Y	SVd Arm	97	0	0,00	97	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Baseline single cytogenetic alterations	Y	Vd Arm	93	1	1,08	92	98,92	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Previously Exposed to Bortezomib	N	SVd Arm	61	0	0,00	61	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Previously Exposed to Bortezomib	N	Vd Arm	62	2	3,23	60	96,77	-	-	-	-	-	-	-	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Previously Exposed to Bortezomib	Y	SVd Arm	134	0	0,00	134	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAESI or SAECI Neuropathy Peripheral	Previously Exposed to Bortezomib	Y	Vd Arm	142	0	0,00	142	100,00	NA	NA	NA	-	-	-	-	NA

Tabelle 7: Vollständige Darstellung der Subgruppenanalysen zu UE nach SOC und PT

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	total	-	SVd Arm	Blood and lymphatic system disorders	Anaemia	195	72	36,92	123	63,08	32,46	26,91	NA	1,75	1,21	2,53	0,0028	NA
Patients with at least one AE	total	-	Vd Arm	Blood and lymphatic system disorders	Anaemia	204	47	23,04	157	76,96	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Gastrointestinal disorders	Abdominal pain	80	5	6,25	75	93,75	NA	NA	NA	3,44	0,64	18,41	0,1280	0,7011
Patients with at least one AE	Gender	Female	Vd Arm	Gastrointestinal disorders	Abdominal pain	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,7011
Patients with at least one AE	Gender	Male	SVd Arm	Gastrointestinal disorders	Abdominal pain	115	5	4,35	110	95,65	NA	NA	NA	5,87	0,68	50,58	0,0684	0,7011
Patients with at least one AE	Gender	Male	Vd Arm	Gastrointestinal disorders	Abdominal pain	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	0,7011
Patients with at least one AE	Age Group	<65	SVd Arm	Gastrointestinal disorders	Abdominal pain	86	4	4,65	82	95,35	NA	NA	NA	4,36	0,48	39,21	0,1521	0,6688
Patients with at least one AE	Age Group	<65	Vd Arm	Gastrointestinal disorders	Abdominal pain	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,6688
Patients with at least one AE	Age Group	>=65	SVd Arm	Gastrointestinal disorders	Abdominal pain	109	6	5,50	103	94,50	NA	NA	NA	2,47	0,61	9,97	0,1902	0,6688
Patients with at least one AE	Age Group	>=65	Vd Arm	Gastrointestinal disorders	Abdominal pain	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	0,6688
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Abdominal pain	173	8	4,62	165	95,38	NA	NA	NA	2,65	0,70	10,03	0,1353	0,9836
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Abdominal pain	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	0,9836
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Abdominal pain	12	2	16,67	10	83,33	NA	NA	NA	2,73	0,23	33,00	0,4142	0,9836
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Abdominal pain	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,9836
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Abdominal pain	163	8	4,91	155	95,09	NA	NA	NA	2,90	0,77	10,94	0,1002	0,9853
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Abdominal pain	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	0,9853
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Abdominal pain	32	2	6,25	30	93,75	NA	NA	NA	2,97	0,27	33,26	0,3536	0,9853
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Abdominal pain	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,9853
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	Abdominal pain	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,7337
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	Abdominal pain	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,7337

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	Abdominal pain	61	4	6,56	57	93,44	NA	NA	NA	3,97	0,44	35,56	0,1831	0,7337
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	Abdominal pain	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,7337
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	Abdominal pain	47	2	4,26	45	95,74	-	-	-	-	-	-	-	0,7337
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	Abdominal pain	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,7337
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	Abdominal pain	69	4	5,80	65	94,20	NA	NA	NA	2,45	0,44	13,65	0,2928	0,7337
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	Abdominal pain	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,7337
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	Abdominal pain	117	4	3,42	113	96,58	NA	NA	NA	2,49	0,45	13,78	0,2806	0,8167
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	Abdominal pain	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	0,8167
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	Abdominal pain	78	6	7,69	72	92,31	NA	NA	NA	3,29	0,65	16,54	0,1273	0,8167
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	Abdominal pain	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,8167
Patients with at least one AE	Race	Races other than White	SVd Arm	Gastrointestinal disorders	Abdominal pain	34	3	8,82	31	91,18	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Gastrointestinal disorders	Abdominal pain	42	1	2,38	41	97,62	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Gastrointestinal disorders	Abdominal pain	161	7	4,35	154	95,65	NA	NA	NA	2,64	0,67	10,33	0,1491	NA
Patients with at least one AE	Race	White	Vd Arm	Gastrointestinal disorders	Abdominal pain	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Abdominal pain	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Abdominal pain	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Abdominal pain	171	9	5,26	162	94,74	NA	NA	NA	2,86	0,86	9,47	0,0734	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Abdominal pain	185	4	2,16	181	97,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	Abdominal pain	48	4	8,33	44	91,67	NA	NA	NA	2,34	0,42	12,95	0,3169	0,7539

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	Abdominal pain	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,7539
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	Abdominal pain	147	6	4,08	141	95,92	NA	NA	NA	3,40	0,68	16,91	0,1116	0,7539
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	Abdominal pain	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,7539
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	Abdominal pain	98	6	6,12	92	93,88	NA	NA	NA	3,46	0,70	17,18	0,1059	0,7286
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	Abdominal pain	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	0,7286
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	Abdominal pain	97	4	4,12	93	95,88	NA	NA	NA	2,28	0,41	12,67	0,3317	0,7286
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	Abdominal pain	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,7286
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	Abdominal pain	98	4	4,08	94	95,92	NA	NA	NA	1,82	0,40	8,33	0,4351	0,3896
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	Abdominal pain	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	0,3896
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	Abdominal pain	97	6	6,19	91	93,81	NA	NA	NA	5,72	0,69	47,71	0,0687	0,3896
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	Abdominal pain	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,3896
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	Abdominal pain	61	7	11,48	54	88,52	NA	NA	NA	3,69	0,74	18,46	0,0894	0,5636
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	Abdominal pain	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,5636
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	Abdominal pain	134	3	2,24	131	97,76	NA	NA	NA	1,81	0,30	10,98	0,5137	0,5636
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	Abdominal pain	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,5636
Patients with at least one AE	total	-	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	195	10	5,13	185	94,87	NA	NA	NA	4,34	0,93	20,21	0,0422	NA
Patients with at least one AE	total	-	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Investigations	Alanine aminotransferase increased	80	4	5,00	76	95,00	NA	NA	NA	1,65	0,36	7,47	0,5130	0,7938
Patients with at least one AE	Gender	Female	Vd Arm	Investigations	Alanine aminotransferase increased	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,7938
Patients with at least one AE	Gender	Male	SVd Arm	Investigations	Alanine aminotransferase increased	115	9	7,83	106	92,17	NA	NA	NA	2,13	0,65	6,97	0,2012	0,7938

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Male	Vd Arm	Investigations	Alanine aminotransferase increased	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,7938
Patients with at least one AE	Age Group	<65	SVd Arm	Investigations	Alanine aminotransferase increased	86	6	6,98	80	93,02	NA	NA	NA	1,56	0,38	6,42	0,5317	0,6716
Patients with at least one AE	Age Group	<65	Vd Arm	Investigations	Alanine aminotransferase increased	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,6716
Patients with at least one AE	Age Group	>=65	SVd Arm	Investigations	Alanine aminotransferase increased	109	7	6,42	102	93,58	NA	NA	NA	2,35	0,68	8,11	0,1647	0,6716
Patients with at least one AE	Age Group	>=65	Vd Arm	Investigations	Alanine aminotransferase increased	129	4	3,10	125	96,90	NA	NA	NA	-	-	-	-	0,6716
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Investigations	Alanine aminotransferase increased	173	13	7,51	160	92,49	NA	NA	NA	2,22	0,83	5,88	0,1014	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Investigations	Alanine aminotransferase increased	174	6	3,45	168	96,55	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Investigations	Alanine aminotransferase increased	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Investigations	Alanine aminotransferase increased	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Investigations	Alanine aminotransferase increased	163	13	7,98	150	92,02	NA	NA	NA	2,26	0,86	5,99	0,0909	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Investigations	Alanine aminotransferase increased	173	6	3,47	167	96,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Investigations	Alanine aminotransferase increased	32	0	0,00	32	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Investigations	Alanine aminotransferase increased	31	1	3,23	30	96,77	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Investigations	Alanine aminotransferase increased	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,1126
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Investigations	Alanine aminotransferase increased	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,1126
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Investigations	Alanine aminotransferase increased	61	4	6,56	57	93,44	NA	NA	NA	0,52	0,12	2,20	0,3673	0,1126
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Investigations	Alanine aminotransferase increased	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,1126
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Investigations	Alanine aminotransferase increased	47	2	4,26	45	95,74	-	-	-	-	-	-	-	0,1126
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Investigations	Alanine aminotransferase increased	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,1126
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Investigations	Alanine aminotransferase increased	69	6	8,70	63	91,30	NA	NA	NA	2,99	0,60	14,94	0,1608	0,1126
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Investigations	Alanine aminotransferase increased	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,1126
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Investigations	Alanine aminotransferase increased	117	7	5,98	110	94,02	NA	NA	NA	1,57	0,49	5,00	0,4430	0,6124
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Investigations	Alanine aminotransferase increased	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,6124

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Investigations	Alanine aminotransferase increased	78	6	7,69	72	92,31	NA	NA	NA	2,62	0,52	13,15	0,2245	0,6124
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Investigations	Alanine aminotransferase increased	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,6124
Patients with at least one AE	Race	Races other than White	SVd Arm	Investigations	Alanine aminotransferase increased	34	0	0,00	34	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Investigations	Alanine aminotransferase increased	42	3	7,14	39	92,86	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Investigations	Alanine aminotransferase increased	161	13	8,07	148	91,93	NA	NA	NA	3,58	1,15	11,14	0,0189	NA
Patients with at least one AE	Race	White	Vd Arm	Investigations	Alanine aminotransferase increased	162	4	2,47	158	97,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Investigations	Alanine aminotransferase increased	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Investigations	Alanine aminotransferase increased	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Investigations	Alanine aminotransferase increased	171	9	5,26	162	94,74	NA	NA	NA	1,70	0,59	4,87	0,3176	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Investigations	Alanine aminotransferase increased	185	6	3,24	179	96,76	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Investigations	Alanine aminotransferase increased	48	5	10,42	43	89,58	NA	NA	NA	1,77	0,42	7,49	0,4340	0,8641
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Investigations	Alanine aminotransferase increased	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,8641
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Investigations	Alanine aminotransferase increased	147	8	5,44	139	94,56	NA	NA	NA	2,08	0,62	6,94	0,2221	0,8641
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Investigations	Alanine aminotransferase increased	157	4	2,55	153	97,45	NA	NA	NA	-	-	-	-	0,8641
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Investigations	Alanine aminotransferase increased	98	6	6,12	92	93,88	NA	NA	NA	1,23	0,37	4,05	0,7304	0,2655
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Investigations	Alanine aminotransferase increased	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,2655
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Investigations	Alanine aminotransferase increased	97	7	7,22	90	92,78	NA	NA	NA	3,80	0,78	18,48	0,0765	0,2655
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Investigations	Alanine aminotransferase increased	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,2655
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Investigations	Alanine aminotransferase increased	98	5	5,10	93	94,90	NA	NA	NA	1,85	0,43	7,89	0,4005	0,9048

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Investigations	Alanine aminotransferase increased	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	0,9048
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Investigations	Alanine aminotransferase increased	97	8	8,25	89	91,75	NA	NA	NA	1,65	0,49	5,50	0,4126	0,9048
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Investigations	Alanine aminotransferase increased	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,9048
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Investigations	Alanine aminotransferase increased	61	7	11,48	54	88,52	NA	NA	NA	2,63	0,67	10,30	0,1492	0,6169
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Investigations	Alanine aminotransferase increased	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,6169
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Investigations	Alanine aminotransferase increased	134	6	4,48	128	95,52	NA	NA	NA	1,63	0,46	5,84	0,4451	0,6169
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Investigations	Alanine aminotransferase increased	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,6169
Patients with at least one AE	total	-	SVd Arm	Blood and lymphatic system disorders	Neutropenia	195	28	14,36	167	85,64	NA	NA	NA	2,76	1,37	5,56	0,0030	NA
Patients with at least one AE	total	-	Vd Arm	Blood and lymphatic system disorders	Neutropenia	204	11	5,39	193	94,61	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Blood and lymphatic system disorders	Anaemia	80	31	38,75	49	61,25	26,91	15,70	NA	1,74	0,97	3,13	0,0604	0,8796
Patients with at least one AE	Gender	Female	Vd Arm	Blood and lymphatic system disorders	Anaemia	91	24	26,37	67	73,63	NA	16,82	NA	-	-	-	-	0,8796
Patients with at least one AE	Gender	Male	SVd Arm	Blood and lymphatic system disorders	Anaemia	115	41	35,65	74	64,35	NA	9,92	NA	1,85	1,11	3,09	0,0173	0,8796
Patients with at least one AE	Gender	Male	Vd Arm	Blood and lymphatic system disorders	Anaemia	113	23	20,35	90	79,65	NA	NA	NA	-	-	-	-	0,8796
Patients with at least one AE	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	Anaemia	86	36	41,86	50	58,14	32,46	9,20	NA	1,99	1,10	3,63	0,0215	0,5475
Patients with at least one AE	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	Anaemia	75	17	22,67	58	77,33	NA	16,82	NA	-	-	-	-	0,5475
Patients with at least one AE	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	Anaemia	109	36	33,03	73	66,97	NA	26,91	NA	1,57	0,96	2,57	0,0678	0,5475
Patients with at least one AE	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	Anaemia	129	30	23,26	99	76,74	NA	NA	NA	-	-	-	-	0,5475
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Anaemia	173	65	37,57	108	62,43	32,46	15,70	NA	1,93	1,28	2,91	0,0014	0,1879
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Anaemia	174	36	20,69	138	79,31	NA	NA	NA	-	-	-	-	0,1879
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Anaemia	12	6	50,00	6	50,00	5,95	1,64	NA	0,76	0,20	2,86	0,6863	0,1879
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Anaemia	16	7	43,75	9	56,25	NA	1,45	NA	-	-	-	-	0,1879

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Anaemia	163	58	35,58	105	64,42	32,46	26,91	NA	1,80	1,19	2,74	0,0051	0,5457
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Anaemia	173	36	20,81	137	79,19	NA	NA	NA	-	-	-	-	0,5457
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Anaemia	32	14	43,75	18	56,25	5,95	2,14	NA	1,36	0,60	3,07	0,4601	0,5457
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Anaemia	31	11	35,48	20	64,52	NA	2,10	NA	-	-	-	-	0,5457
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	Anaemia	18	5	27,78	13	72,22	NA	NA	NA	3,44	0,38	31,07	0,2412	0,6014
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	Anaemia	17	3	17,65	14	82,35	NA	10,38	NA	-	-	-	-	0,6014
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	Anaemia	61	22	36,07	39	63,93	26,91	10,64	NA	1,37	0,72	2,60	0,3306	0,6014
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	Anaemia	64	17	26,56	47	73,44	NA	NA	NA	-	-	-	-	0,6014
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	Anaemia	47	14	29,79	33	70,21	NA	NA	NA	1,61	0,71	3,67	0,2531	0,6014
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	Anaemia	53	10	18,87	43	81,13	NA	NA	NA	-	-	-	-	0,6014
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	Anaemia	69	31	44,93	38	55,07	15,70	3,98	NA	2,35	1,29	4,27	0,0040	0,6014
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	Anaemia	70	17	24,29	53	75,71	NA	NA	NA	-	-	-	-	0,6014
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	Anaemia	117	38	32,48	79	67,52	NA	26,91	NA	1,50	0,93	2,44	0,0975	0,3287
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	Anaemia	136	30	22,06	106	77,94	NA	NA	NA	-	-	-	-	0,3287
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	Anaemia	78	34	43,59	44	56,41	15,70	5,95	NA	2,20	1,22	3,96	0,0073	0,3287
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	Anaemia	68	17	25,00	51	75,00	NA	16,82	NA	-	-	-	-	0,3287
Patients with at least one AE	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	Anaemia	34	13	38,24	21	61,76	NA	4,34	NA	1,54	0,68	3,48	0,2966	0,6838
Patients with at least one AE	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	Anaemia	42	13	30,95	29	69,05	NA	10,94	NA	-	-	-	-	0,6838
Patients with at least one AE	Race	White	SVd Arm	Blood and lymphatic system disorders	Anaemia	161	59	36,65	102	63,35	32,46	15,70	NA	1,86	1,22	2,86	0,0037	0,6838
Patients with at least one AE	Race	White	Vd Arm	Blood and lymphatic system disorders	Anaemia	162	34	20,99	128	79,01	NA	NA	NA	-	-	-	-	0,6838
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Anaemia	6	4	66,67	2	33,33	2,09	0,03	NA	2,33	0,24	22,78	0,4547	0,7856

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Anaemia	5	2	40,00	3	60,00	NA	2,20	NA	-	-	-	-	0,7856
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Anaemia	171	62	36,26	109	63,74	32,46	26,91	NA	1,69	1,14	2,50	0,0081	0,7856
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Anaemia	185	43	23,24	142	76,76	NA	NA	NA	-	-	-	-	0,7856
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	Anaemia	48	22	45,83	26	54,17	32,46	2,56	NA	3,13	1,39	7,09	0,0039	0,1044
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	Anaemia	47	8	17,02	39	82,98	NA	NA	NA	-	-	-	-	0,1044
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	Anaemia	147	50	34,01	97	65,99	NA	15,70	NA	1,46	0,96	2,23	0,0739	0,1044
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	Anaemia	157	39	24,84	118	75,16	NA	NA	NA	-	-	-	-	0,1044
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	Anaemia	98	42	42,86	56	57,14	15,70	6,21	NA	2,34	1,39	3,93	0,0010	0,1049
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	Anaemia	104	22	21,15	82	78,85	NA	NA	NA	-	-	-	-	0,1049
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	Anaemia	97	30	30,93	67	69,07	NA	32,46	NA	1,26	0,74	2,15	0,3921	0,1049
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	Anaemia	100	25	25,00	75	75,00	NA	NA	NA	-	-	-	-	0,1049
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	Anaemia	98	38	38,78	60	61,22	32,46	7,62	NA	2,02	1,20	3,39	0,0072	0,4488
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	Anaemia	111	24	21,62	87	78,38	NA	NA	NA	-	-	-	-	0,4488
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	Anaemia	97	34	35,05	63	64,95	NA	26,91	NA	1,51	0,88	2,59	0,1332	0,4488
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	Anaemia	93	23	24,73	70	75,27	NA	18,46	NA	-	-	-	-	0,4488
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	Anaemia	61	25	40,98	36	59,02	26,91	6,97	NA	2,33	1,13	4,82	0,0184	0,3494
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	Anaemia	62	11	17,74	51	82,26	NA	NA	NA	-	-	-	-	0,3494
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	Anaemia	134	47	35,07	87	64,93	NA	15,70	NA	1,56	1,00	2,42	0,0465	0,3494

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	Anaemia	142	36	25,35	106	74,65	NA	NA	NA	-	-	-	-	0,3494
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Blood and lymphatic system disorders	Anaemia	195	32	16,41	163	83,59	NA	NA	NA	1,77	1,00	3,11	0,0456	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Blood and lymphatic system disorders	Anaemia	204	20	9,80	184	90,20	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Blood and lymphatic system disorders	Anaemia	80	12	15,00	68	85,00	NA	32,69	NA	1,89	0,76	4,68	0,1649	0,8637
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Blood and lymphatic system disorders	Anaemia	91	11	12,09	80	87,91	NA	NA	NA	-	-	-	-	0,8637
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Blood and lymphatic system disorders	Anaemia	115	20	17,39	95	82,61	NA	NA	NA	2,10	0,95	4,61	0,0599	0,8637
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Blood and lymphatic system disorders	Anaemia	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	0,8637
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	Anaemia	86	14	16,28	72	83,72	NA	NA	NA	2,36	0,86	6,52	0,0889	0,5432
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	Anaemia	75	6	8,00	69	92,00	NA	NA	NA	-	-	-	-	0,5432
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	Anaemia	109	18	16,51	91	83,49	NA	NA	NA	1,61	0,80	3,26	0,1815	0,5432
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	Anaemia	129	14	10,85	115	89,15	NA	NA	NA	-	-	-	-	0,5432
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Anaemia	173	28	16,18	145	83,82	NA	NA	NA	1,90	1,00	3,58	0,0448	0,7040
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Anaemia	174	15	8,62	159	91,38	NA	NA	NA	-	-	-	-	0,7040
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Anaemia	12	4	33,33	8	66,67	NA	4,17	NA	1,38	0,30	6,30	0,6789	0,7040
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Anaemia	16	4	25,00	12	75,00	NA	NA	NA	-	-	-	-	0,7040
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Anaemia	163	22	13,50	141	86,50	NA	NA	NA	1,66	0,84	3,27	0,1399	0,8546

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Anaemia	173	14	8,09	159	91,91	NA	NA	NA	-	-	-	-	0,8546
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Anaemia	32	10	31,25	22	68,75	NA	4,17	NA	1,86	0,65	5,33	0,2399	0,8546
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Anaemia	31	6	19,35	25	80,65	NA	NA	NA	-	-	-	-	0,8546
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	Anaemia	18	2	11,11	16	88,89	NA	NA	NA	1,86	0,17	20,75	0,6100	0,6683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	Anaemia	17	2	11,76	15	88,24	NA	10,38	NA	-	-	-	-	0,6683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	Anaemia	61	11	18,03	50	81,97	NA	NA	NA	1,82	0,69	4,77	0,2192	0,6683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	Anaemia	64	7	10,94	57	89,06	NA	NA	NA	-	-	-	-	0,6683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	Anaemia	47	3	6,38	44	93,62	NA	NA	NA	0,64	0,11	3,83	0,6188	0,6683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	Anaemia	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,6683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	Anaemia	69	16	23,19	53	76,81	NA	32,69	NA	2,26	0,96	5,37	0,0570	0,6683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	Anaemia	70	8	11,43	62	88,57	NA	NA	NA	-	-	-	-	0,6683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	Anaemia	117	13	11,11	104	88,89	NA	NA	NA	1,11	0,50	2,47	0,7940	0,1594
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	Anaemia	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,1594
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	Anaemia	78	19	24,36	59	75,64	NA	32,69	NA	2,60	1,08	6,25	0,0267	0,1594
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	Anaemia	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,1594
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	Anaemia	34	9	26,47	25	73,53	NA	NA	NA	2,02	0,69	5,91	0,1916	0,8447

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	Anaemia	42	6	14,29	36	85,71	NA	NA	NA	-	-	-	-	0,8447
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Blood and lymphatic system disorders	Anaemia	161	23	14,29	138	85,71	NA	NA	NA	1,78	0,90	3,51	0,0931	0,8447
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Blood and lymphatic system disorders	Anaemia	162	14	8,64	148	91,36	NA	NA	NA	-	-	-	-	0,8447
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Anaemia	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Anaemia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Anaemia	171	26	15,20	145	84,80	NA	NA	NA	1,55	0,85	2,82	0,1511	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Anaemia	185	19	10,27	166	89,73	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	Anaemia	48	9	18,75	39	81,25	NA	32,69	NA	3,02	0,80	11,43	0,0876	0,3696
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	Anaemia	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,3696
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	Anaemia	147	23	15,65	124	84,35	NA	NA	NA	1,54	0,82	2,90	0,1767	0,3696
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	Anaemia	157	17	10,83	140	89,17	NA	NA	NA	-	-	-	-	0,3696
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	Anaemia	98	22	22,45	76	77,55	NA	NA	NA	2,91	1,33	6,38	0,0053	0,0494
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	Anaemia	104	9	8,65	95	91,35	NA	NA	NA	-	-	-	-	0,0494
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	Anaemia	97	10	10,31	87	89,69	NA	NA	NA	0,90	0,38	2,14	0,8120	0,0494
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	Anaemia	100	11	11,00	89	89,00	NA	NA	NA	-	-	-	-	0,0494

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	Anaemia	98	16	16,33	82	83,67	NA	NA	NA	2,34	0,98	5,63	0,0501	0,4019
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	Anaemia	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,4019
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	Anaemia	97	16	16,49	81	83,51	NA	NA	NA	1,42	0,65	3,09	0,3745	0,4019
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	Anaemia	93	12	12,90	81	87,10	NA	NA	NA	-	-	-	-	0,4019
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	Anaemia	61	10	16,39	51	83,61	NA	32,69	NA	3,13	0,84	11,71	0,0754	0,3636
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	Anaemia	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,3636
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	Anaemia	134	22	16,42	112	83,58	NA	NA	NA	1,58	0,83	3,03	0,1604	0,3636
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	Anaemia	142	17	11,97	125	88,03	NA	NA	NA	-	-	-	-	0,3636
Patients with at least one AE	total	-	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	195	114	58,46	81	41,54	3,71	1,64	7,43	3,15	2,25	4,42	0,0000	NA
Patients with at least one AE	total	-	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	204	50	24,51	154	75,49	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	80	4	5,00	76	95,00	NA	NA	NA	0,51	0,15	1,76	0,2752	0,5511
Patients with at least one AE	Gender	Female	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	91	10	10,99	81	89,01	NA	26,74	NA	-	-	-	-	0,5511
Patients with at least one AE	Gender	Male	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	115	9	7,83	106	92,17	NA	NA	NA	0,81	0,32	2,03	0,6505	0,5511
Patients with at least one AE	Gender	Male	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	113	10	8,85	103	91,15	NA	NA	NA	-	-	-	-	0,5511
Patients with at least one AE	Age Group	<65	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	86	2	2,33	84	97,67	NA	NA	NA	0,29	0,06	1,48	0,1156	0,1732
Patients with at least one AE	Age Group	<65	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	75	6	8,00	69	92,00	NA	26,74	NA	-	-	-	-	0,1732
Patients with at least one AE	Age Group	>=65	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	109	11	10,09	98	89,91	NA	NA	NA	1,03	0,46	2,30	0,9469	0,1732

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	>=65	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	129	14	10,85	115	89,15	NA	NA	NA	-	-	-	-	0,1732
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	173	11	6,36	162	93,64	NA	NA	NA	0,65	0,30	1,42	0,2817	0,4190
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	174	16	9,20	158	90,80	NA	NA	NA	-	-	-	-	0,4190
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	12	2	16,67	10	83,33	NA	NA	NA	1,58	0,22	11,59	0,6496	0,4190
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,4190
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	163	10	6,13	153	93,87	NA	NA	NA	0,57	0,26	1,25	0,1583	0,3606
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	173	18	10,40	155	89,60	NA	NA	NA	-	-	-	-	0,3606
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	32	3	9,38	29	90,62	NA	NA	NA	1,49	0,22	9,94	0,6762	0,3606
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,3606
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	18	3	16,67	15	83,33	NA	20,53	NA	1,05	0,15	7,52	0,9643	0,7156
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	17	4	23,53	13	76,47	10,68	9,40	NA	-	-	-	-	0,7156
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	61	4	6,56	57	93,44	NA	NA	NA	0,44	0,13	1,52	0,1852	0,7156
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	64	9	14,06	55	85,94	NA	19,91	NA	-	-	-	-	0,7156
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	47	2	4,26	45	95,74	NA	NA	NA	1,16	0,19	7,21	0,8771	0,7156
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	53	3	5,66	50	94,34	NA	22,70	NA	-	-	-	-	0,7156
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	69	4	5,80	65	94,20	NA	NA	NA	1,15	0,28	4,68	0,8478	0,7156

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	70	4	5,71	66	94,29	NA	NA	NA	-	-	-	-	0,7156
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	117	9	7,69	108	92,31	NA	NA	NA	0,66	0,28	1,54	0,3322	0,7201
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	136	15	11,03	121	88,97	NA	NA	NA	-	-	-	-	0,7201
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	78	4	5,13	74	94,87	NA	NA	NA	0,88	0,23	3,32	0,8493	0,7201
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,7201
Patients with at least one AE	Race	Races other than White	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	34	2	5,88	32	94,12	NA	25,00	NA	0,44	0,08	2,37	0,3288	0,4461
Patients with at least one AE	Race	Races other than White	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	42	7	16,67	35	83,33	26,74	25,95	NA	-	-	-	-	0,4461
Patients with at least one AE	Race	White	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	161	11	6,83	150	93,17	NA	NA	NA	0,91	0,40	2,07	0,8271	0,4461
Patients with at least one AE	Race	White	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	162	13	8,02	149	91,98	NA	NA	NA	-	-	-	-	0,4461
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	171	10	5,85	161	94,15	NA	NA	NA	0,57	0,26	1,23	0,1471	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	185	20	10,81	165	89,19	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	48	5	10,42	43	89,58	NA	NA	NA	0,93	0,26	3,27	0,9063	0,5800
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	47	5	10,64	42	89,36	NA	25,95	NA	-	-	-	-	0,5800

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	147	8	5,44	139	94,56	NA	NA	NA	0,60	0,25	1,43	0,2453	0,5800
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	157	15	9,55	142	90,45	NA	NA	NA	-	-	-	-	0,5800
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	98	5	5,10	93	94,90	NA	NA	NA	0,55	0,18	1,66	0,2830	0,5954
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	104	9	8,65	95	91,35	NA	26,74	NA	-	-	-	-	0,5954
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	97	8	8,25	89	91,75	NA	NA	NA	0,81	0,32	2,03	0,6552	0,5954
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	100	11	11,00	89	89,00	NA	NA	NA	-	-	-	-	0,5954
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	98	7	7,14	91	92,86	NA	NA	NA	0,67	0,26	1,75	0,4104	0,9931
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	111	12	10,81	99	89,19	NA	25,95	NA	-	-	-	-	0,9931
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	97	6	6,19	91	93,81	NA	NA	NA	0,67	0,23	1,97	0,4695	0,9931
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	93	8	8,60	85	91,40	NA	NA	NA	-	-	-	-	0,9931
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	61	6	9,84	55	90,16	NA	NA	NA	1,02	0,32	3,23	0,9731	0,5498
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	62	7	11,29	55	88,71	NA	22,70	NA	-	-	-	-	0,5498
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	134	7	5,22	127	94,78	NA	NA	NA	0,65	0,26	1,65	0,3591	0,5498
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	142	13	9,15	129	90,85	NA	NA	NA	-	-	-	-	0,5498
Patients with at least one AE	total	-	SVd Arm	Blood and lymphatic system disorders	-	195	131	67,18	64	32,82	1,64	1,41	3,78	2,39	1,80	3,18	0,0000	NA
Patients with at least one AE	total	-	Vd Arm	Blood and lymphatic system disorders	-	204	77	37,75	127	62,25	NA	18,46	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Investigations	Aspartate aminotransferase increased	80	2	2,50	78	97,50	NA	NA	NA	1,27	0,18	9,16	0,8120	0,7255

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Female	Vd Arm	Investigations	Aspartate aminotransferase increased	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,7255
Patients with at least one AE	Gender	Male	SVd Arm	Investigations	Aspartate aminotransferase increased	115	8	6,96	107	93,04	NA	NA	NA	1,92	0,57	6,44	0,2806	0,7255
Patients with at least one AE	Gender	Male	Vd Arm	Investigations	Aspartate aminotransferase increased	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,7255
Patients with at least one AE	Age Group	<65	SVd Arm	Investigations	Aspartate aminotransferase increased	86	6	6,98	80	93,02	NA	NA	NA	2,79	0,55	14,11	0,1968	0,5303
Patients with at least one AE	Age Group	<65	Vd Arm	Investigations	Aspartate aminotransferase increased	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,5303
Patients with at least one AE	Age Group	>=65	SVd Arm	Investigations	Aspartate aminotransferase increased	109	4	3,67	105	96,33	NA	NA	NA	1,41	0,35	5,69	0,6319	0,5303
Patients with at least one AE	Age Group	>=65	Vd Arm	Investigations	Aspartate aminotransferase increased	129	4	3,10	125	96,90	NA	NA	NA	-	-	-	-	0,5303
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Investigations	Aspartate aminotransferase increased	173	9	5,20	164	94,80	NA	NA	NA	1,87	0,62	5,65	0,2621	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Investigations	Aspartate aminotransferase increased	174	5	2,87	169	97,13	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Investigations	Aspartate aminotransferase increased	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Investigations	Aspartate aminotransferase increased	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Investigations	Aspartate aminotransferase increased	163	10	6,13	153	93,87	NA	NA	NA	2,81	0,87	9,06	0,0708	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Investigations	Aspartate aminotransferase increased	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Investigations	Aspartate aminotransferase increased	32	0	0,00	32	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Investigations	Aspartate aminotransferase increased	31	2	6,45	29	93,55	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Investigations	Aspartate aminotransferase increased	18	2	11,11	16	88,89	-	-	-	-	-	-	-	0,1074

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Investigations	Aspartate aminotransferase increased	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,1074
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Investigations	Aspartate aminotransferase increased	61	1	1,64	60	98,36	NA	NA	NA	0,20	0,02	1,82	0,1150	0,1074
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Investigations	Aspartate aminotransferase increased	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,1074
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Investigations	Aspartate aminotransferase increased	47	2	4,26	45	95,74	NA	NA	NA	1,90	0,17	21,01	0,5963	0,1074
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Investigations	Aspartate aminotransferase increased	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,1074
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Investigations	Aspartate aminotransferase increased	69	5	7,25	64	92,75	NA	NA	NA	5,25	0,61	45,17	0,0921	0,1074
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Investigations	Aspartate aminotransferase increased	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,1074
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Investigations	Aspartate aminotransferase increased	117	5	4,27	112	95,73	NA	NA	NA	1,16	0,33	4,06	0,8217	0,2882
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Investigations	Aspartate aminotransferase increased	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,2882
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Investigations	Aspartate aminotransferase increased	78	5	6,41	73	93,59	NA	NA	NA	4,48	0,52	38,95	0,1380	0,2882
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Investigations	Aspartate aminotransferase increased	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,2882
Patients with at least one AE	Race	Races other than White	SVd Arm	Investigations	Aspartate aminotransferase increased	34	0	0,00	34	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Investigations	Aspartate aminotransferase increased	42	2	4,76	40	95,24	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Investigations	Aspartate aminotransferase increased	161	10	6,21	151	93,79	NA	NA	NA	2,89	0,89	9,43	0,0660	NA
Patients with at least one AE	Race	White	Vd Arm	Investigations	Aspartate aminotransferase increased	162	4	2,47	158	97,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Investigations	Aspartate aminotransferase increased	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Investigations	Aspartate aminotransferase increased	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Investigations	Aspartate aminotransferase increased	171	8	4,68	163	95,32	NA	NA	NA	1,95	0,62	6,10	0,2458	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Investigations	Aspartate aminotransferase increased	185	5	2,70	180	97,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Investigations	Aspartate aminotransferase increased	48	5	10,42	43	89,58	NA	NA	NA	2,75	0,53	14,42	0,2122	0,5521
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Investigations	Aspartate aminotransferase increased	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,5521
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Investigations	Aspartate aminotransferase increased	147	5	3,40	142	96,60	NA	NA	NA	1,45	0,38	5,44	0,5826	0,5521
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Investigations	Aspartate aminotransferase increased	157	4	2,55	153	97,45	NA	NA	NA	-	-	-	-	0,5521
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Investigations	Aspartate aminotransferase increased	98	4	4,08	94	95,92	NA	NA	NA	1,05	0,26	4,20	0,9505	0,2445
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Investigations	Aspartate aminotransferase increased	104	4	3,85	100	96,15	NA	NA	NA	-	-	-	-	0,2445
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Investigations	Aspartate aminotransferase increased	97	6	6,19	91	93,81	NA	NA	NA	3,71	0,74	18,66	0,0896	0,2445
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Investigations	Aspartate aminotransferase increased	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,2445
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Investigations	Aspartate aminotransferase increased	98	5	5,10	93	94,90	NA	NA	NA	1,43	0,38	5,42	0,5950	0,6609
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Investigations	Aspartate aminotransferase increased	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,6609
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Investigations	Aspartate aminotransferase increased	97	5	5,15	92	94,85	NA	NA	NA	2,30	0,44	11,98	0,3086	0,6609
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Investigations	Aspartate aminotransferase increased	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,6609

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Investigations	Aspartate aminotransferase increased	61	6	9,84	55	90,16	NA	NA	NA	3,35	0,67	16,82	0,1198	0,3534
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Investigations	Aspartate aminotransferase increased	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,3534
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Investigations	Aspartate aminotransferase increased	134	4	2,99	130	97,01	NA	NA	NA	1,22	0,30	4,93	0,7799	0,3534
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Investigations	Aspartate aminotransferase increased	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,3534
Patients with at least one AE	total	-	SVd Arm	Cardiac disorders	Tachycardia	195	10	5,13	185	94,87	NA	NA	NA	3,38	0,93	12,28	0,0499	NA
Patients with at least one AE	total	-	Vd Arm	Cardiac disorders	Tachycardia	204	3	1,47	201	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	General disorders and administration site conditions	Asthenia	80	21	26,25	59	73,75	NA	24,15	NA	2,15	1,03	4,48	0,0381	0,7197
Patients with at least one AE	Gender	Female	Vd Arm	General disorders and administration site conditions	Asthenia	91	12	13,19	79	86,81	NA	NA	NA	-	-	-	-	0,7197
Patients with at least one AE	Gender	Male	SVd Arm	General disorders and administration site conditions	Asthenia	115	28	24,35	87	75,65	NA	NA	NA	1,80	0,95	3,40	0,0678	0,7197
Patients with at least one AE	Gender	Male	Vd Arm	General disorders and administration site conditions	Asthenia	113	15	13,27	98	86,73	NA	NA	NA	-	-	-	-	0,7197
Patients with at least one AE	Age Group	<65	SVd Arm	General disorders and administration site conditions	Asthenia	86	21	24,42	65	75,58	NA	24,15	NA	2,20	0,98	4,96	0,0514	0,9797
Patients with at least one AE	Age Group	<65	Vd Arm	General disorders and administration site conditions	Asthenia	75	10	13,33	65	86,67	NA	NA	NA	-	-	-	-	0,9797
Patients with at least one AE	Age Group	>=65	SVd Arm	General disorders and administration site conditions	Asthenia	109	28	25,69	81	74,31	NA	NA	NA	2,23	1,20	4,16	0,0096	0,9797
Patients with at least one AE	Age Group	>=65	Vd Arm	General disorders and administration site conditions	Asthenia	129	17	13,18	112	86,82	NA	NA	NA	-	-	-	-	0,9797
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Asthenia	173	45	26,01	128	73,99	NA	NA	NA	1,89	1,14	3,14	0,0124	0,6999
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Asthenia	174	24	13,79	150	86,21	NA	NA	NA	-	-	-	-	0,6999
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Asthenia	12	3	25,00	9	75,00	NA	NA	NA	3,05	0,28	32,81	0,3401	0,6999

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Asthenia	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,6999
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Asthenia	163	38	23,31	125	76,69	NA	NA	NA	1,82	1,07	3,07	0,0239	0,7289
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Asthenia	173	23	13,29	150	86,71	NA	NA	NA	-	-	-	-	0,7289
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Asthenia	32	11	34,38	21	65,62	13,70	5,59	NA	2,28	0,70	7,47	0,1615	0,7289
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Asthenia	31	4	12,90	27	87,10	NA	NA	NA	-	-	-	-	0,7289
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	General disorders and administration site conditions	Asthenia	18	2	11,11	16	88,89	-	-	-	-	-	-	-	0,0222
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	General disorders and administration site conditions	Asthenia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,0222
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	General disorders and administration site conditions	Asthenia	61	11	18,03	50	81,97	NA	NA	NA	0,80	0,36	1,78	0,5843	0,0222
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	General disorders and administration site conditions	Asthenia	64	15	23,44	49	76,56	NA	NA	NA	-	-	-	-	0,0222
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	General disorders and administration site conditions	Asthenia	47	15	31,91	32	68,09	NA	10,61	NA	7,18	1,62	31,85	0,0026	0,0222
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	General disorders and administration site conditions	Asthenia	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,0222
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	General disorders and administration site conditions	Asthenia	69	21	30,43	48	69,57	NA	24,15	NA	2,30	1,07	4,95	0,0281	0,0222
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	General disorders and administration site conditions	Asthenia	70	10	14,29	60	85,71	NA	NA	NA	-	-	-	-	0,0222
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	General disorders and administration site conditions	Asthenia	117	27	23,08	90	76,92	NA	NA	NA	2,16	1,13	4,14	0,0174	0,6421
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	General disorders and administration site conditions	Asthenia	136	15	11,03	121	88,97	NA	NA	NA	-	-	-	-	0,6421
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	General disorders and administration site conditions	Asthenia	78	22	28,21	56	71,79	NA	24,15	NA	1,72	0,84	3,52	0,1346	0,6421

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	General disorders and administration site conditions	Asthenia	68	12	17,65	56	82,35	NA	NA	NA	-	-	-	-	0,6421
Patients with at least one AE	Race	Races other than White	SVd Arm	General disorders and administration site conditions	Asthenia	34	10	29,41	24	70,59	NA	NA	NA	1,24	0,49	3,14	0,6443	0,2324
Patients with at least one AE	Race	Races other than White	Vd Arm	General disorders and administration site conditions	Asthenia	42	10	23,81	32	76,19	NA	NA	NA	-	-	-	-	0,2324
Patients with at least one AE	Race	White	SVd Arm	General disorders and administration site conditions	Asthenia	161	39	24,22	122	75,78	NA	NA	NA	2,43	1,35	4,38	0,0024	0,2324
Patients with at least one AE	Race	White	Vd Arm	General disorders and administration site conditions	Asthenia	162	17	10,49	145	89,51	NA	NA	NA	-	-	-	-	0,2324
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Asthenia	6	4	66,67	2	33,33	1,26	0,10	NA	2,89	0,28	29,61	0,3518	0,7616
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Asthenia	5	1	20,00	4	80,00	NA	NA	NA	-	-	-	-	0,7616
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Asthenia	171	42	24,56	129	75,44	NA	NA	NA	2,00	1,19	3,36	0,0074	0,7616
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Asthenia	185	23	12,43	162	87,57	NA	NA	NA	-	-	-	-	0,7616
Patients with at least one AE	Prior PI therapies	N	SVd Arm	General disorders and administration site conditions	Asthenia	48	11	22,92	37	77,08	NA	NA	NA	1,65	0,60	4,51	0,3278	0,7008
Patients with at least one AE	Prior PI therapies	N	Vd Arm	General disorders and administration site conditions	Asthenia	47	6	12,77	41	87,23	NA	NA	NA	-	-	-	-	0,7008
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	General disorders and administration site conditions	Asthenia	147	38	25,85	109	74,15	NA	NA	NA	2,06	1,20	3,54	0,0076	0,7008
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	General disorders and administration site conditions	Asthenia	157	21	13,38	136	86,62	NA	NA	NA	-	-	-	-	0,7008
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	General disorders and administration site conditions	Asthenia	98	25	25,51	73	74,49	NA	NA	NA	1,65	0,87	3,11	0,1199	0,4315
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	General disorders and administration site conditions	Asthenia	104	16	15,38	88	84,62	NA	NA	NA	-	-	-	-	0,4315

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	General disorders and administration site conditions	Asthenia	97	24	24,74	73	75,26	NA	NA	NA	2,43	1,17	5,03	0,0137	0,4315
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	General disorders and administration site conditions	Asthenia	100	11	11,00	89	89,00	NA	NA	NA	-	-	-	-	0,4315
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	General disorders and administration site conditions	Asthenia	98	26	26,53	72	73,47	NA	24,15	NA	1,56	0,85	2,87	0,1485	0,3287
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	General disorders and administration site conditions	Asthenia	111	19	17,12	92	82,88	NA	NA	NA	-	-	-	-	0,3287
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	General disorders and administration site conditions	Asthenia	97	23	23,71	74	76,29	NA	NA	NA	2,59	1,15	5,86	0,0174	0,3287
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	General disorders and administration site conditions	Asthenia	93	8	8,60	85	91,40	NA	NA	NA	-	-	-	-	0,3287
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	General disorders and administration site conditions	Asthenia	61	15	24,59	46	75,41	NA	NA	NA	1,80	0,74	4,35	0,1881	0,7094
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	General disorders and administration site conditions	Asthenia	62	8	12,90	54	87,10	NA	NA	NA	-	-	-	-	0,7094
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	General disorders and administration site conditions	Asthenia	134	34	25,37	100	74,63	NA	NA	NA	2,19	1,24	3,88	0,0057	0,7094
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	General disorders and administration site conditions	Asthenia	142	19	13,38	123	86,62	NA	NA	NA	-	-	-	-	0,7094
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	General disorders and administration site conditions	Asthenia	195	16	8,21	179	91,79	NA	NA	NA	1,86	0,82	4,22	0,1328	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	General disorders and administration site conditions	Asthenia	204	9	4,41	195	95,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	General disorders and administration site conditions	Asthenia	80	5	6,25	75	93,75	NA	NA	NA	1,34	0,36	5,03	0,6651	0,5795
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	General disorders and administration site conditions	Asthenia	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,5795
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	General disorders and administration site conditions	Asthenia	115	11	9,57	104	90,43	NA	NA	NA	2,16	0,75	6,24	0,1445	0,5795
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	General disorders and administration site conditions	Asthenia	113	5	4,42	108	95,58	NA	NA	NA	-	-	-	-	0,5795

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	General disorders and administration site conditions	Asthenia	86	6	6,98	80	93,02	NA	NA	NA	2,52	0,49	13,07	0,2554	0,7798
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	General disorders and administration site conditions	Asthenia	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,7798
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	General disorders and administration site conditions	Asthenia	109	10	9,17	99	90,83	NA	NA	NA	1,92	0,72	5,12	0,1841	0,7798
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	General disorders and administration site conditions	Asthenia	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	0,7798
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Asthenia	173	15	8,67	158	91,33	NA	NA	NA	1,89	0,79	4,52	0,1472	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Asthenia	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Asthenia	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Asthenia	16	1	6,25	15	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Asthenia	163	12	7,36	151	92,64	NA	NA	NA	1,81	0,71	4,62	0,2061	0,8074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Asthenia	173	7	4,05	166	95,95	NA	NA	NA	-	-	-	-	0,8074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Asthenia	32	4	12,50	28	87,50	NA	NA	NA	2,45	0,26	22,93	0,4181	0,8074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Asthenia	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,8074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	General disorders and administration site conditions	Asthenia	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,0416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	General disorders and administration site conditions	Asthenia	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	0,0416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	General disorders and administration site conditions	Asthenia	61	1	1,64	60	98,36	NA	NA	NA	0,19	0,02	1,56	0,0835	0,0416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	General disorders and administration site conditions	Asthenia	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,0416

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	General disorders and administration site conditions	Asthenia	47	8	17,02	39	82,98	-	-	-	-	-	-	-	0,0416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	General disorders and administration site conditions	Asthenia	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,0416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	General disorders and administration site conditions	Asthenia	69	7	10,14	62	89,86	NA	NA	NA	2,60	0,65	10,33	0,1607	0,0416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	General disorders and administration site conditions	Asthenia	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	0,0416
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	General disorders and administration site conditions	Asthenia	117	9	7,69	108	92,31	NA	NA	NA	1,74	0,60	5,02	0,2982	0,7074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	General disorders and administration site conditions	Asthenia	136	6	4,41	130	95,59	NA	NA	NA	-	-	-	-	0,7074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	General disorders and administration site conditions	Asthenia	78	7	8,97	71	91,03	NA	NA	NA	2,44	0,60	9,82	0,1980	0,7074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	General disorders and administration site conditions	Asthenia	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,7074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	General disorders and administration site conditions	Asthenia	34	3	8,82	31	91,18	NA	NA	NA	1,19	0,26	5,43	0,8217	0,3727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	General disorders and administration site conditions	Asthenia	42	4	9,52	38	90,48	NA	NA	NA	-	-	-	-	0,3727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	General disorders and administration site conditions	Asthenia	161	13	8,07	148	91,93	NA	NA	NA	2,75	0,96	7,87	0,0493	0,3727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	General disorders and administration site conditions	Asthenia	162	5	3,09	157	96,91	NA	NA	NA	-	-	-	-	0,3727
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Asthenia	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Asthenia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Asthenia	171	14	8,19	157	91,81	NA	NA	NA	1,93	0,80	4,63	0,1357	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Asthenia	185	8	4,32	177	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	General disorders and administration site conditions	Asthenia	48	3	6,25	45	93,75	NA	NA	NA	1,36	0,23	8,17	0,7354	0,7042
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	General disorders and administration site conditions	Asthenia	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,7042
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	General disorders and administration site conditions	Asthenia	147	13	8,84	134	91,16	NA	NA	NA	2,01	0,80	5,06	0,1306	0,7042
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	General disorders and administration site conditions	Asthenia	157	7	4,46	150	95,54	NA	NA	NA	-	-	-	-	0,7042
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	General disorders and administration site conditions	Asthenia	98	5	5,10	93	94,90	NA	NA	NA	1,65	0,39	6,92	0,4883	0,8450
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	General disorders and administration site conditions	Asthenia	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,8450
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	General disorders and administration site conditions	Asthenia	97	11	11,34	86	88,66	NA	NA	NA	1,97	0,72	5,35	0,1777	0,8450
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	General disorders and administration site conditions	Asthenia	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,8450
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	General disorders and administration site conditions	Asthenia	98	9	9,18	89	90,82	NA	NA	NA	1,83	0,64	5,27	0,2543	0,9878
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	General disorders and administration site conditions	Asthenia	111	6	5,41	105	94,59	NA	NA	NA	-	-	-	-	0,9878
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	General disorders and administration site conditions	Asthenia	97	7	7,22	90	92,78	NA	NA	NA	1,86	0,48	7,20	0,3626	0,9878
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	General disorders and administration site conditions	Asthenia	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,9878
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	General disorders and administration site conditions	Asthenia	61	4	6,56	57	93,44	NA	NA	NA	1,36	0,30	6,14	0,6857	0,6142
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	General disorders and administration site conditions	Asthenia	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,6142
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	General disorders and administration site conditions	Asthenia	134	12	8,96	122	91,04	NA	NA	NA	2,17	0,81	5,80	0,1153	0,6142

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	General disorders and administration site conditions	Asthenia	142	6	4,23	136	95,77	NA	NA	NA	-	-	-	-	0,6142
Patients with at least one AE	total	-	SVd Arm	Cardiac disorders	-	195	35	17,95	160	82,05	NA	36,60	NA	2,24	1,23	4,08	0,0069	NA
Patients with at least one AE	total	-	Vd Arm	Cardiac disorders	-	204	16	7,84	188	92,16	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	80	11	13,75	69	86,25	NA	NA	NA	1,21	0,51	2,90	0,6638	0,6825
Patients with at least one AE	Gender	Female	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	91	10	10,99	81	89,01	NA	NA	NA	-	-	-	-	0,6825
Patients with at least one AE	Gender	Male	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	115	19	16,52	96	83,48	NA	NA	NA	0,97	0,51	1,84	0,9202	0,6825
Patients with at least one AE	Gender	Male	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	113	19	16,81	94	83,19	NA	NA	NA	-	-	-	-	0,6825
Patients with at least one AE	Age Group	<65	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	86	10	11,63	76	88,37	NA	NA	NA	0,59	0,25	1,37	0,2151	0,0661
Patients with at least one AE	Age Group	<65	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	75	13	17,33	62	82,67	NA	NA	NA	-	-	-	-	0,0661
Patients with at least one AE	Age Group	>=65	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	109	20	18,35	89	81,65	NA	32,16	NA	1,62	0,83	3,15	0,1546	0,0661
Patients with at least one AE	Age Group	>=65	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	129	16	12,40	113	87,60	NA	NA	NA	-	-	-	-	0,0661
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	173	27	15,61	146	84,39	NA	NA	NA	1,06	0,61	1,82	0,8406	0,6282
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	174	26	14,94	148	85,06	NA	NA	NA	-	-	-	-	0,6282
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	12	2	16,67	10	83,33	NA	NA	NA	0,62	0,08	4,91	0,6521	0,6282
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,6282
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	163	26	15,95	137	84,05	NA	NA	NA	1,09	0,63	1,89	0,7527	0,7481
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	173	26	15,03	147	84,97	NA	NA	NA	-	-	-	-	0,7481

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	32	4	12,50	28	87,50	NA	NA	NA	1,42	0,31	6,55	0,6481	0,7481
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,7481
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	18	3	16,67	15	83,33	NA	NA	NA	0,86	0,17	4,44	0,8580	0,8622
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	17	3	17,65	14	82,35	NA	9,40	NA	-	-	-	-	0,8622
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	61	14	22,95	47	77,05	NA	32,16	NA	1,30	0,59	2,84	0,5158	0,8622
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	64	12	18,75	52	81,25	NA	NA	NA	-	-	-	-	0,8622
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	47	5	10,64	42	89,36	NA	NA	NA	0,74	0,23	2,34	0,6020	0,8622
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	53	7	13,21	46	86,79	NA	NA	NA	-	-	-	-	0,8622
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	69	8	11,59	61	88,41	NA	NA	NA	1,21	0,43	3,40	0,7219	0,8622
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	70	7	10,00	63	90,00	NA	NA	NA	-	-	-	-	0,8622
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	117	18	15,38	99	84,62	NA	NA	NA	0,97	0,51	1,84	0,9331	0,4747
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	136	21	15,44	115	84,56	NA	NA	NA	-	-	-	-	0,4747
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	78	12	15,38	66	84,62	NA	NA	NA	1,46	0,58	3,66	0,4143	0,4747
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	68	8	11,76	60	88,24	NA	NA	NA	-	-	-	-	0,4747
Patients with at least one AE	Race	Races other than White	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	34	9	26,47	25	73,53	NA	NA	NA	1,06	0,37	3,04	0,9172	0,8994
Patients with at least one AE	Race	Races other than White	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	42	11	26,19	31	73,81	16,26	14,39	NA	-	-	-	-	0,8994

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	161	21	13,04	140	86,96	NA	NA	NA	1,15	0,61	2,17	0,6763	0,8994
Patients with at least one AE	Race	White	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	162	18	11,11	144	88,89	NA	NA	NA	-	-	-	-	0,8994
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	171	25	14,62	146	85,38	NA	NA	NA	1,05	0,60	1,81	0,8690	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	185	27	14,59	158	85,41	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	48	6	12,50	42	87,50	NA	NA	NA	1,32	0,40	4,37	0,6435	0,7570
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,7570
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	147	24	16,33	123	83,67	NA	NA	NA	1,07	0,61	1,90	0,8030	0,7570
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	157	24	15,29	133	84,71	NA	NA	NA	-	-	-	-	0,7570
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	98	15	15,31	83	84,69	NA	32,16	NA	0,98	0,48	1,99	0,9629	0,6070
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	104	16	15,38	88	84,62	NA	NA	NA	-	-	-	-	0,6070
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	97	15	15,46	82	84,54	NA	NA	NA	1,29	0,61	2,72	0,5054	0,6070
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	100	13	13,00	87	87,00	NA	NA	NA	-	-	-	-	0,6070
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	98	18	18,37	80	81,63	NA	32,16	NA	1,51	0,76	3,02	0,2363	0,1515

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	111	15	13,51	96	86,49	NA	NA	NA	-	-	-	-	0,1515
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	97	12	12,37	85	87,63	NA	NA	NA	0,71	0,33	1,54	0,3804	0,1515
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	93	14	15,05	79	84,95	NA	NA	NA	-	-	-	-	0,1515
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	61	8	13,11	53	86,89	NA	NA	NA	0,94	0,34	2,61	0,8987	0,6923
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	62	9	14,52	53	85,48	NA	NA	NA	-	-	-	-	0,6923
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	134	22	16,42	112	83,58	NA	32,16	NA	1,19	0,65	2,19	0,5751	0,6923
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	142	20	14,08	122	85,92	NA	NA	NA	-	-	-	-	0,6923
Patients with at least one AE	total	-	SVd Arm	Ear and labyrinth disorders	-	195	14	7,18	181	92,82	NA	NA	NA	3,87	1,27	11,82	0,0106	NA
Patients with at least one AE	total	-	Vd Arm	Ear and labyrinth disorders	-	204	4	1,96	200	98,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Investigations	Blood creatinine increased	80	5	6,25	75	93,75	NA	NA	NA	2,55	0,60	10,85	0,1888	0,5226
Patients with at least one AE	Gender	Female	Vd Arm	Investigations	Blood creatinine increased	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,5226
Patients with at least one AE	Gender	Male	SVd Arm	Investigations	Blood creatinine increased	115	6	5,22	109	94,78	NA	NA	NA	1,36	0,38	4,87	0,6338	0,5226
Patients with at least one AE	Gender	Male	Vd Arm	Investigations	Blood creatinine increased	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,5226
Patients with at least one AE	Age Group	<65	SVd Arm	Investigations	Blood creatinine increased	86	4	4,65	82	95,35	NA	NA	NA	1,49	0,26	8,53	0,6531	0,8210
Patients with at least one AE	Age Group	<65	Vd Arm	Investigations	Blood creatinine increased	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,8210
Patients with at least one AE	Age Group	>=65	SVd Arm	Investigations	Blood creatinine increased	109	7	6,42	102	93,58	NA	NA	NA	1,90	0,59	6,05	0,2719	0,8210
Patients with at least one AE	Age Group	>=65	Vd Arm	Investigations	Blood creatinine increased	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,8210
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Investigations	Blood creatinine increased	173	11	6,36	162	93,64	NA	NA	NA	2,53	0,87	7,35	0,0766	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Investigations	Blood creatinine increased	174	5	2,87	169	97,13	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Investigations	Blood creatinine increased	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Investigations	Blood creatinine increased	16	1	6,25	15	93,75	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Investigations	Blood creatinine increased	163	10	6,13	153	93,87	NA	NA	NA	1,96	0,71	5,41	0,1867	0,6930
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Investigations	Blood creatinine increased	173	6	3,47	167	96,53	NA	NA	NA	-	-	-	-	0,6930
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Investigations	Blood creatinine increased	32	1	3,12	31	96,88	NA	NA	NA	1,08	0,07	17,30	0,9566	0,6930
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Investigations	Blood creatinine increased	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,6930
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Investigations	Blood creatinine increased	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,8812
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Investigations	Blood creatinine increased	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,8812
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Investigations	Blood creatinine increased	61	7	11,48	54	88,52	NA	NA	NA	2,31	0,56	9,50	0,2353	0,8812
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Investigations	Blood creatinine increased	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,8812
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Investigations	Blood creatinine increased	47	1	2,13	46	97,87	NA	NA	NA	1,15	0,07	18,59	0,9191	0,8812
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Investigations	Blood creatinine increased	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,8812
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Investigations	Blood creatinine increased	69	3	4,35	66	95,65	NA	NA	NA	1,50	0,25	9,14	0,6548	0,8812
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Investigations	Blood creatinine increased	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,8812
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Investigations	Blood creatinine increased	117	7	5,98	110	94,02	NA	NA	NA	1,69	0,54	5,36	0,3639	0,9426
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Investigations	Blood creatinine increased	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,9426
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Investigations	Blood creatinine increased	78	4	5,13	74	94,87	NA	NA	NA	1,83	0,33	10,09	0,4828	0,9426
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Investigations	Blood creatinine increased	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,9426
Patients with at least one AE	Race	Races other than White	SVd Arm	Investigations	Blood creatinine increased	34	2	5,88	32	94,12	NA	NA	NA	2,86	0,22	37,23	0,4091	0,7237
Patients with at least one AE	Race	Races other than White	Vd Arm	Investigations	Blood creatinine increased	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,7237
Patients with at least one AE	Race	White	SVd Arm	Investigations	Blood creatinine increased	161	9	5,59	152	94,41	NA	NA	NA	1,73	0,61	4,90	0,2928	0,7237
Patients with at least one AE	Race	White	Vd Arm	Investigations	Blood creatinine increased	162	6	3,70	156	96,30	NA	NA	NA	-	-	-	-	0,7237
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Investigations	Blood creatinine increased	6	4	66,67	2	33,33	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Investigations	Blood creatinine increased	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Investigations	Blood creatinine increased	171	7	4,09	164	95,91	NA	NA	NA	1,52	0,50	4,62	0,4530	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Investigations	Blood creatinine increased	185	6	3,24	179	96,76	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Investigations	Blood creatinine increased	48	4	8,33	44	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Investigations	Blood creatinine increased	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Investigations	Blood creatinine increased	147	7	4,76	140	95,24	NA	NA	NA	1,15	0,40	3,28	0,7977	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Investigations	Blood creatinine increased	157	7	4,46	150	95,54	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Investigations	Blood creatinine increased	98	4	4,08	94	95,92	NA	NA	NA	1,38	0,31	6,15	0,6744	0,6429
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Investigations	Blood creatinine increased	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,6429
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Investigations	Blood creatinine increased	97	7	7,22	90	92,78	NA	NA	NA	2,18	0,63	7,49	0,2054	0,6429
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Investigations	Blood creatinine increased	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,6429
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Investigations	Blood creatinine increased	98	7	7,14	91	92,86	NA	NA	NA	2,03	0,59	7,00	0,2519	0,6306
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Investigations	Blood creatinine increased	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,6306
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Investigations	Blood creatinine increased	97	4	4,12	93	95,88	NA	NA	NA	1,26	0,28	5,65	0,7614	0,6306
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Investigations	Blood creatinine increased	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,6306
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Investigations	Blood creatinine increased	61	4	6,56	57	93,44	NA	NA	NA	4,83	0,53	43,94	0,1235	0,3108
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Investigations	Blood creatinine increased	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,3108
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Investigations	Blood creatinine increased	134	7	5,22	127	94,78	NA	NA	NA	1,35	0,45	4,04	0,5876	0,3108

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Investigations	Blood creatinine increased	142	6	4,23	136	95,77	NA	NA	NA	-	-	-	-	0,3108
Patients with at least one AE	total	-	SVd Arm	Eye disorders	Cataract	195	43	22,05	152	77,95	26,91	17,41	NA	3,25	1,77	5,99	0,0001	NA
Patients with at least one AE	total	-	Vd Arm	Eye disorders	Cataract	204	14	6,86	190	93,14	NA	41,20	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Infections and infestations	Bronchitis	80	17	21,25	63	78,75	NA	22,08	NA	1,28	0,58	2,81	0,5357	0,9654
Patients with at least one AE	Gender	Female	Vd Arm	Infections and infestations	Bronchitis	91	14	15,38	77	84,62	NA	NA	NA	-	-	-	-	0,9654
Patients with at least one AE	Gender	Male	SVd Arm	Infections and infestations	Bronchitis	115	8	6,96	107	93,04	NA	NA	NA	1,24	0,45	3,45	0,6735	0,9654
Patients with at least one AE	Gender	Male	Vd Arm	Infections and infestations	Bronchitis	113	7	6,19	106	93,81	NA	NA	NA	-	-	-	-	0,9654
Patients with at least one AE	Age Group	<65	SVd Arm	Infections and infestations	Bronchitis	86	9	10,47	77	89,53	NA	NA	NA	1,75	0,52	5,83	0,3586	0,5653
Patients with at least one AE	Age Group	<65	Vd Arm	Infections and infestations	Bronchitis	75	4	5,33	71	94,67	NA	NA	NA	-	-	-	-	0,5653
Patients with at least one AE	Age Group	>=65	SVd Arm	Infections and infestations	Bronchitis	109	16	14,68	93	85,32	NA	NA	NA	1,16	0,58	2,33	0,6734	0,5653
Patients with at least one AE	Age Group	>=65	Vd Arm	Infections and infestations	Bronchitis	129	17	13,18	112	86,82	NA	NA	NA	-	-	-	-	0,5653
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Bronchitis	173	24	13,87	149	86,13	NA	NA	NA	1,26	0,68	2,34	0,4621	0,8893
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Bronchitis	174	18	10,34	156	89,66	NA	NA	NA	-	-	-	-	0,8893
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Bronchitis	12	1	8,33	11	91,67	NA	NA	NA	1,00	0,04	24,55	1,0000	0,8893
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Bronchitis	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,8893
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Bronchitis	163	22	13,50	141	86,50	NA	NA	NA	1,27	0,67	2,41	0,4580	0,3932
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Bronchitis	173	17	9,83	156	90,17	NA	NA	NA	-	-	-	-	0,3932
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Bronchitis	32	3	9,38	29	90,62	NA	NA	NA	0,62	0,13	2,86	0,5341	0,3932
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Bronchitis	31	4	12,90	27	87,10	NA	NA	NA	-	-	-	-	0,3932
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Bronchitis	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,4604
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Bronchitis	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,4604
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Bronchitis	61	6	9,84	55	90,16	NA	22,08	NA	0,78	0,24	2,50	0,6760	0,4604
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Bronchitis	64	8	12,50	56	87,50	NA	24,08	NA	-	-	-	-	0,4604
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Bronchitis	47	10	21,28	37	78,72	NA	NA	NA	1,75	0,58	5,26	0,3106	0,4604
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Bronchitis	53	5	9,43	48	90,57	NA	NA	NA	-	-	-	-	0,4604

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Bronchitis	69	6	8,70	63	91,30	NA	NA	NA	0,72	0,25	2,08	0,5396	0,4604
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Bronchitis	70	8	11,43	62	88,57	NA	NA	NA	-	-	-	-	0,4604
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Bronchitis	117	21	17,95	96	82,05	NA	NA	NA	1,45	0,74	2,84	0,2733	0,3857
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Bronchitis	136	16	11,76	120	88,24	NA	NA	NA	-	-	-	-	0,3857
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Bronchitis	78	4	5,13	74	94,87	NA	NA	NA	0,75	0,20	2,83	0,6734	0,3857
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Bronchitis	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,3857
Patients with at least one AE	Race	Races other than White	SVd Arm	Infections and infestations	Bronchitis	34	2	5,88	32	94,12	NA	NA	NA	0,93	0,15	5,85	0,9404	0,8040
Patients with at least one AE	Race	Races other than White	Vd Arm	Infections and infestations	Bronchitis	42	3	7,14	39	92,86	NA	NA	NA	-	-	-	-	0,8040
Patients with at least one AE	Race	White	SVd Arm	Infections and infestations	Bronchitis	161	23	14,29	138	85,71	NA	NA	NA	1,19	0,63	2,24	0,5853	0,8040
Patients with at least one AE	Race	White	Vd Arm	Infections and infestations	Bronchitis	162	18	11,11	144	88,89	NA	NA	NA	-	-	-	-	0,8040
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Bronchitis	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Bronchitis	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Bronchitis	171	21	12,28	150	87,72	NA	NA	NA	1,13	0,60	2,11	0,7087	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Bronchitis	185	19	10,27	166	89,73	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Infections and infestations	Bronchitis	48	8	16,67	40	83,33	NA	NA	NA	1,49	0,48	4,58	0,4848	0,6330
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Infections and infestations	Bronchitis	47	5	10,64	42	89,36	NA	18,43	NA	-	-	-	-	0,6330
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Infections and infestations	Bronchitis	147	17	11,56	130	88,44	NA	NA	NA	1,08	0,54	2,15	0,8259	0,6330
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Infections and infestations	Bronchitis	157	16	10,19	141	89,81	NA	NA	NA	-	-	-	-	0,6330
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Bronchitis	98	12	12,24	86	87,76	NA	NA	NA	1,00	0,45	2,24	0,9921	0,5678

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Bronchitis	104	12	11,54	92	88,46	NA	NA	NA	-	-	-	-	0,5678
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Bronchitis	97	13	13,40	84	86,60	NA	NA	NA	1,41	0,60	3,33	0,4255	0,5678
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Bronchitis	100	9	9,00	91	91,00	NA	NA	NA	-	-	-	-	0,5678
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Bronchitis	98	10	10,20	88	89,80	NA	NA	NA	0,99	0,42	2,38	0,9904	0,6312
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Bronchitis	111	11	9,91	100	90,09	NA	NA	NA	-	-	-	-	0,6312
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Bronchitis	97	15	15,46	82	84,54	NA	NA	NA	1,33	0,59	2,99	0,4868	0,6312
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Bronchitis	93	10	10,75	83	89,25	NA	NA	NA	-	-	-	-	0,6312
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Bronchitis	61	8	13,11	53	86,89	NA	NA	NA	1,26	0,43	3,66	0,6684	0,8954
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Bronchitis	62	6	9,68	56	90,32	NA	NA	NA	-	-	-	-	0,8954
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Bronchitis	134	17	12,69	117	87,31	NA	NA	NA	1,16	0,58	2,33	0,6806	0,8954
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Bronchitis	142	15	10,56	127	89,44	NA	NA	NA	-	-	-	-	0,8954
Patients with at least one AE	total	-	SVd Arm	Eye disorders	Vision blurred	195	13	6,67	182	93,33	NA	NA	NA	1,58	0,67	3,71	0,2883	NA
Patients with at least one AE	total	-	Vd Arm	Eye disorders	Vision blurred	204	9	4,41	195	95,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Eye disorders	Cataract	80	17	21,25	63	78,75	NA	16,99	NA	4,24	1,36	13,18	0,0077	0,6077
Patients with at least one AE	Gender	Female	Vd Arm	Eye disorders	Cataract	91	5	5,49	86	94,51	NA	41,20	NA	-	-	-	-	0,6077
Patients with at least one AE	Gender	Male	SVd Arm	Eye disorders	Cataract	115	26	22,61	89	77,39	26,91	20,21	NA	2,96	1,36	6,43	0,0043	0,6077
Patients with at least one AE	Gender	Male	Vd Arm	Eye disorders	Cataract	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	0,6077
Patients with at least one AE	Age Group	<65	SVd Arm	Eye disorders	Cataract	86	27	31,40	59	68,60	20,21	13,83	NA	4,04	1,63	10,06	0,0013	0,5389
Patients with at least one AE	Age Group	<65	Vd Arm	Eye disorders	Cataract	75	7	9,33	68	90,67	41,20	41,20	NA	-	-	-	-	0,5389
Patients with at least one AE	Age Group	>=65	SVd Arm	Eye disorders	Cataract	109	16	14,68	93	85,32	NA	NA	NA	2,70	1,10	6,67	0,0251	0,5389
Patients with at least one AE	Age Group	>=65	Vd Arm	Eye disorders	Cataract	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	0,5389
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Eye disorders	Cataract	173	37	21,39	136	78,61	NA	20,21	NA	2,87	1,48	5,56	0,0012	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Eye disorders	Cataract	174	12	6,90	162	93,10	41,20	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Eye disorders	Cataract	12	3	25,00	9	75,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Eye disorders	Cataract	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Eye disorders	Cataract	163	37	22,70	126	77,30	30,95	17,41	NA	2,90	1,53	5,49	0,0007	0,3952
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Eye disorders	Cataract	173	13	7,51	160	92,49	NA	41,20	NA	-	-	-	-	0,3952
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Eye disorders	Cataract	32	6	18,75	26	81,25	26,91	8,90	NA	7,78	0,87	69,31	0,0334	0,3952
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Eye disorders	Cataract	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,3952
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Eye disorders	Cataract	18	5	27,78	13	72,22	-	-	-	-	-	-	-	0,6970
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Eye disorders	Cataract	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,6970
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Eye disorders	Cataract	61	12	19,67	49	80,33	NA	10,64	NA	3,77	1,30	10,94	0,0092	0,6970
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Eye disorders	Cataract	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,6970
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Eye disorders	Cataract	47	8	17,02	39	82,98	-	-	-	-	-	-	-	0,6970
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Eye disorders	Cataract	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,6970
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Eye disorders	Cataract	69	18	26,09	51	73,91	25,82	16,99	NA	2,86	1,17	6,99	0,0159	0,6970
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Eye disorders	Cataract	70	8	11,43	62	88,57	41,20	NA	NA	-	-	-	-	0,6970
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Eye disorders	Cataract	117	20	17,09	97	82,91	NA	20,30	NA	4,11	1,53	11,04	0,0025	0,6992
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Eye disorders	Cataract	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,6992
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Eye disorders	Cataract	78	23	29,49	55	70,51	17,41	13,83	NA	3,19	1,40	7,24	0,0036	0,6992
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Eye disorders	Cataract	68	9	13,24	59	86,76	41,20	NA	NA	-	-	-	-	0,6992
Patients with at least one AE	Race	Races other than White	SVd Arm	Eye disorders	Cataract	34	9	26,47	25	73,53	NA	8,31	NA	3,02	0,73	12,54	0,1139	0,9488
Patients with at least one AE	Race	Races other than White	Vd Arm	Eye disorders	Cataract	42	5	11,90	37	88,10	NA	23,13	NA	-	-	-	-	0,9488
Patients with at least one AE	Race	White	SVd Arm	Eye disorders	Cataract	161	34	21,12	127	78,88	26,91	17,41	NA	3,18	1,51	6,70	0,0013	0,9488
Patients with at least one AE	Race	White	Vd Arm	Eye disorders	Cataract	162	9	5,56	153	94,44	NA	41,20	NA	-	-	-	-	0,9488
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Eye disorders	Cataract	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Eye disorders	Cataract	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Eye disorders	Cataract	171	38	22,22	133	77,78	26,91	17,41	NA	3,49	1,81	6,73	0,0001	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Eye disorders	Cataract	185	12	6,49	173	93,51	NA	41,20	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Eye disorders	Cataract	48	12	25,00	36	75,00	26,91	13,83	NA	1,32	0,50	3,44	0,5735	0,0297
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Eye disorders	Cataract	47	7	14,89	40	85,11	NA	NA	NA	-	-	-	-	0,0297
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Eye disorders	Cataract	147	31	21,09	116	78,91	25,82	17,41	NA	5,36	2,35	12,23	0,0000	0,0297
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Eye disorders	Cataract	157	7	4,46	150	95,54	NA	41,20	NA	-	-	-	-	0,0297
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Eye disorders	Cataract	98	25	25,51	73	74,49	17,41	11,96	NA	4,09	1,75	9,55	0,0004	0,4114
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Eye disorders	Cataract	104	7	6,73	97	93,27	41,20	NA	NA	-	-	-	-	0,4114
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Eye disorders	Cataract	97	18	18,56	79	81,44	NA	20,30	NA	2,45	1,01	5,93	0,0405	0,4114
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Eye disorders	Cataract	100	7	7,00	93	93,00	NA	NA	NA	-	-	-	-	0,4114
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Eye disorders	Cataract	98	23	23,47	75	76,53	26,91	13,83	NA	3,03	1,37	6,68	0,0041	0,9491
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Eye disorders	Cataract	111	9	8,11	102	91,89	NA	41,20	NA	-	-	-	-	0,9491
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Eye disorders	Cataract	97	20	20,62	77	79,38	25,82	17,41	NA	3,16	1,17	8,48	0,0164	0,9491
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Eye disorders	Cataract	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,9491
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Eye disorders	Cataract	61	16	26,23	45	73,77	26,91	13,37	NA	1,59	0,63	3,99	0,3226	0,0889
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Eye disorders	Cataract	62	7	11,29	55	88,71	NA	NA	NA	-	-	-	-	0,0889
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Eye disorders	Cataract	134	27	20,15	107	79,85	30,95	20,21	NA	4,68	2,02	10,80	0,0001	0,0889
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Eye disorders	Cataract	142	7	4,93	135	95,07	41,20	41,20	NA	-	-	-	-	0,0889
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Eye disorders	Cataract	195	22	11,28	173	88,72	NA	30,95	NA	5,83	1,98	17,14	0,0003	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Eye disorders	Cataract	204	4	1,96	200	98,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Eye disorders	Cataract	80	8	10,00	72	90,00	NA	NA	NA	7,82	0,92	66,31	0,0293	0,6272

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Eye disorders	Cataract	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Eye disorders	Cataract	115	14	12,17	101	87,83	NA	26,91	NA	4,22	1,18	15,08	0,0167	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Eye disorders	Cataract	113	3	2,65	110	97,35	NA	NA	NA	-	-	-	-	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Eye disorders	Cataract	86	14	16,28	72	83,72	30,95	20,30	NA	3,41	0,94	12,47	0,0492	0,3849
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Eye disorders	Cataract	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,3849
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Eye disorders	Cataract	109	8	7,34	101	92,66	NA	NA	NA	10,15	1,26	81,93	0,0076	0,3849
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Eye disorders	Cataract	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	0,3849
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Eye disorders	Cataract	173	21	12,14	152	87,86	NA	NA	NA	5,09	1,72	15,08	0,0011	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Eye disorders	Cataract	174	4	2,30	170	97,70	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Eye disorders	Cataract	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Eye disorders	Cataract	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Eye disorders	Cataract	163	20	12,27	143	87,73	NA	30,95	NA	5,26	1,77	15,56	0,0009	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Eye disorders	Cataract	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Eye disorders	Cataract	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Eye disorders	Cataract	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Eye disorders	Cataract	18	4	22,22	14	77,78	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Eye disorders	Cataract	17	1	5,88	16	94,12	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Eye disorders	Cataract	61	8	13,11	53	86,89	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Eye disorders	Cataract	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Eye disorders	Cataract	47	2	4,26	45	95,74	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Eye disorders	Cataract	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Eye disorders	Cataract	69	8	11,59	61	88,41	NA	26,91	NA	2,70	0,67	10,91	0,1482	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Eye disorders	Cataract	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Eye disorders	Cataract	117	10	8,55	107	91,45	NA	NA	NA	10,81	1,37	85,29	0,0050	0,4756
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Eye disorders	Cataract	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,4756
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Eye disorders	Cataract	78	12	15,38	66	84,62	NA	25,82	NA	4,44	1,20	16,41	0,0156	0,4756
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Eye disorders	Cataract	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,4756
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Eye disorders	Cataract	34	3	8,82	31	91,18	NA	NA	NA	1,17	0,11	12,98	0,8967	0,1754
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Eye disorders	Cataract	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,1754
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Eye disorders	Cataract	161	19	11,80	142	88,20	NA	30,95	NA	8,23	1,89	35,88	0,0009	0,1754
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Eye disorders	Cataract	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	0,1754
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Eye disorders	Cataract	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Eye disorders	Cataract	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Eye disorders	Cataract	171	18	10,53	153	89,47	NA	30,95	NA	4,93	1,64	14,81	0,0017	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Eye disorders	Cataract	185	4	2,16	181	97,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Eye disorders	Cataract	48	7	14,58	41	85,42	NA	NA	NA	2,65	0,51	13,71	0,2279	0,2744
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Eye disorders	Cataract	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,2744
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Eye disorders	Cataract	147	15	10,20	132	89,80	NA	25,82	NA	9,10	2,07	40,02	0,0004	0,2744
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Eye disorders	Cataract	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,2744
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Eye disorders	Cataract	98	13	13,27	85	86,73	NA	25,82	NA	4,90	1,38	17,46	0,0067	0,6539
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Eye disorders	Cataract	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,6539
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Eye disorders	Cataract	97	9	9,28	88	90,72	NA	NA	NA	8,57	1,06	69,04	0,0163	0,6539
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Eye disorders	Cataract	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,6539
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Eye disorders	Cataract	98	11	11,22	87	88,78	NA	30,95	NA	5,77	1,21	27,49	0,0143	0,8530
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Eye disorders	Cataract	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,8530
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Eye disorders	Cataract	97	11	11,34	86	88,66	NA	25,82	NA	4,69	1,02	21,51	0,0295	0,8530
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Eye disorders	Cataract	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,8530

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Eye disorders	Cataract	61	11	18,03	50	81,97	NA	26,91	NA	3,16	0,64	15,71	0,1390	0,5111
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Eye disorders	Cataract	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,5111
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Eye disorders	Cataract	134	11	8,21	123	91,79	NA	30,95	NA	6,62	1,46	30,09	0,0049	0,5111
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Eye disorders	Cataract	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,5111
Patients with at least one AE	total	-	SVd Arm	Eye disorders	Visual impairment	195	14	7,18	181	92,82	NA	NA	NA	3,54	1,15	10,92	0,0194	NA
Patients with at least one AE	total	-	Vd Arm	Eye disorders	Visual impairment	204	4	1,96	200	98,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Psychiatric disorders	Confusional state	80	8	10,00	72	90,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Female	Vd Arm	Psychiatric disorders	Confusional state	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Male	SVd Arm	Psychiatric disorders	Confusional state	115	8	6,96	107	93,04	NA	NA	NA	4,49	0,94	21,34	0,0395	NA
Patients with at least one AE	Gender	Male	Vd Arm	Psychiatric disorders	Confusional state	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Age Group	<65	SVd Arm	Psychiatric disorders	Confusional state	86	0	0,00	86	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Age Group	<65	Vd Arm	Psychiatric disorders	Confusional state	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Age Group	>=65	SVd Arm	Psychiatric disorders	Confusional state	109	16	14,68	93	85,32	NA	NA	NA	10,64	2,43	46,49	0,0001	NA
Patients with at least one AE	Age Group	>=65	Vd Arm	Psychiatric disorders	Confusional state	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Psychiatric disorders	Confusional state	173	15	8,67	158	91,33	NA	NA	NA	7,81	1,78	34,27	0,0013	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Psychiatric disorders	Confusional state	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Psychiatric disorders	Confusional state	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Psychiatric disorders	Confusional state	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Psychiatric disorders	Confusional state	163	16	9,82	147	90,18	NA	NA	NA	16,79	2,22	126,64	0,0002	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Psychiatric disorders	Confusional state	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Psychiatric disorders	Confusional state	32	0	0,00	32	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Psychiatric disorders	Confusional state	31	1	3,23	30	96,77	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Psychiatric disorders	Confusional state	18	4	22,22	14	77,78	NA	7,46	NA	3,76	0,42	33,88	0,2059	NA
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Psychiatric disorders	Confusional state	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Psychiatric disorders	Confusional state	61	12	19,67	49	80,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Psychiatric disorders	Confusional state	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Psychiatric disorders	Confusional state	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Psychiatric disorders	Confusional state	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Psychiatric disorders	Confusional state	69	0	0,00	69	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Psychiatric disorders	Confusional state	70	1	1,43	69	98,57	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Psychiatric disorders	Confusional state	117	13	11,11	104	88,89	NA	NA	NA	7,55	1,69	33,70	0,0019	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Psychiatric disorders	Confusional state	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Psychiatric disorders	Confusional state	78	3	3,85	75	96,15	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Psychiatric disorders	Confusional state	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	SVd Arm	Psychiatric disorders	Confusional state	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Psychiatric disorders	Confusional state	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Psychiatric disorders	Confusional state	161	15	9,32	146	90,68	NA	NA	NA	7,03	1,60	30,83	0,0027	NA
Patients with at least one AE	Race	White	Vd Arm	Psychiatric disorders	Confusional state	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Psychiatric disorders	Confusional state	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Psychiatric disorders	Confusional state	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Psychiatric disorders	Confusional state	171	14	8,19	157	91,81	NA	NA	NA	7,61	1,72	33,53	0,0016	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Psychiatric disorders	Confusional state	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Psychiatric disorders	Confusional state	48	4	8,33	44	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Psychiatric disorders	Confusional state	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Psychiatric disorders	Confusional state	147	12	8,16	135	91,84	NA	NA	NA	6,49	1,45	29,06	0,0048	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Psychiatric disorders	Confusional state	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Psychiatric disorders	Confusional state	98	9	9,18	89	90,82	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Psychiatric disorders	Confusional state	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Psychiatric disorders	Confusional state	97	7	7,22	90	92,78	NA	NA	NA	3,61	0,75	17,44	0,0874	NA
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Psychiatric disorders	Confusional state	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Psychiatric disorders	Confusional state	98	6	6,12	92	93,88	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Psychiatric disorders	Confusional state	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Psychiatric disorders	Confusional state	97	10	10,31	87	89,69	NA	NA	NA	4,20	0,92	19,20	0,0446	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Psychiatric disorders	Confusional state	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Psychiatric disorders	Confusional state	61	5	8,20	56	91,80	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Psychiatric disorders	Confusional state	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Psychiatric disorders	Confusional state	134	11	8,21	123	91,79	NA	NA	NA	5,83	1,29	26,38	0,0095	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Psychiatric disorders	Confusional state	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Eye disorders	-	195	78	40,00	117	60,00	12,52	10,55	20,04	2,02	1,38	2,96	0,0002	NA
Patients with at least one AE	total	-	Vd Arm	Eye disorders	-	204	43	21,08	161	78,92	41,20	23,13	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Gastrointestinal disorders	Constipation	80	12	15,00	68	85,00	NA	NA	NA	0,83	0,38	1,80	0,6364	0,5583
Patients with at least one AE	Gender	Female	Vd Arm	Gastrointestinal disorders	Constipation	91	17	18,68	74	81,32	NA	35,75	NA	-	-	-	-	0,5583
Patients with at least one AE	Gender	Male	SVd Arm	Gastrointestinal disorders	Constipation	115	21	18,26	94	81,74	NA	NA	NA	1,12	0,60	2,08	0,7283	0,5583
Patients with at least one AE	Gender	Male	Vd Arm	Gastrointestinal disorders	Constipation	113	19	16,81	94	83,19	NA	NA	NA	-	-	-	-	0,5583
Patients with at least one AE	Age Group	<65	SVd Arm	Gastrointestinal disorders	Constipation	86	13	15,12	73	84,88	NA	NA	NA	0,73	0,34	1,58	0,4291	0,3976
Patients with at least one AE	Age Group	<65	Vd Arm	Gastrointestinal disorders	Constipation	75	14	18,67	61	81,33	NA	35,75	NA	-	-	-	-	0,3976
Patients with at least one AE	Age Group	>=65	SVd Arm	Gastrointestinal disorders	Constipation	109	20	18,35	89	81,65	NA	NA	NA	1,12	0,61	2,08	0,7117	0,3976
Patients with at least one AE	Age Group	>=65	Vd Arm	Gastrointestinal disorders	Constipation	129	22	17,05	107	82,95	NA	NA	NA	-	-	-	-	0,3976
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Constipation	173	31	17,92	142	82,08	NA	NA	NA	1,04	0,63	1,73	0,8712	0,5413
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Constipation	174	30	17,24	144	82,76	NA	NA	NA	-	-	-	-	0,5413
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Constipation	12	1	8,33	11	91,67	NA	NA	NA	0,46	0,03	6,09	0,5488	0,5413

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Constipation	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,5413
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Constipation	163	31	19,02	132	80,98	NA	NA	NA	1,00	0,61	1,63	0,9849	0,6193
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Constipation	173	33	19,08	140	80,92	NA	NA	NA	-	-	-	-	0,6193
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Constipation	32	2	6,25	30	93,75	NA	NA	NA	0,62	0,10	3,84	0,6003	0,6193
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Constipation	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,6193
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	Constipation	18	4	22,22	14	77,78	NA	NA	NA	0,84	0,22	3,19	0,8003	0,4167
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	Constipation	17	6	35,29	11	64,71	NA	1,61	NA	-	-	-	-	0,4167
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	Constipation	61	20	32,79	41	67,21	NA	6,67	NA	1,47	0,75	2,88	0,2612	0,4167
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	Constipation	64	15	23,44	49	76,56	NA	NA	NA	-	-	-	-	0,4167
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	Constipation	47	2	4,26	45	95,74	NA	NA	NA	0,43	0,08	2,22	0,2974	0,4167
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	Constipation	53	5	9,43	48	90,57	NA	35,75	NA	-	-	-	-	0,4167
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	Constipation	69	7	10,14	62	89,86	NA	NA	NA	0,70	0,27	1,85	0,4734	0,4167
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	Constipation	70	10	14,29	60	85,71	NA	NA	NA	-	-	-	-	0,4167
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	Constipation	117	19	16,24	98	83,76	NA	NA	NA	0,83	0,46	1,52	0,5558	0,5405
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	Constipation	136	25	18,38	111	81,62	NA	35,75	NA	-	-	-	-	0,5405
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	Constipation	78	14	17,95	64	82,05	NA	NA	NA	1,14	0,52	2,51	0,7476	0,5405
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	Constipation	68	11	16,18	57	83,82	NA	NA	NA	-	-	-	-	0,5405
Patients with at least one AE	Race	Races other than White	SVd Arm	Gastrointestinal disorders	Constipation	34	8	23,53	26	76,47	NA	NA	NA	0,95	0,36	2,52	0,9120	0,9477
Patients with at least one AE	Race	Races other than White	Vd Arm	Gastrointestinal disorders	Constipation	42	9	21,43	33	78,57	NA	NA	NA	-	-	-	-	0,9477
Patients with at least one AE	Race	White	SVd Arm	Gastrointestinal disorders	Constipation	161	25	15,53	136	84,47	NA	NA	NA	0,91	0,53	1,58	0,7400	0,9477
Patients with at least one AE	Race	White	Vd Arm	Gastrointestinal disorders	Constipation	162	27	16,67	135	83,33	NA	NA	NA	-	-	-	-	0,9477
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Constipation	6	1	16,67	5	83,33	NA	NA	NA	0,71	0,04	11,79	0,8084	0,7879

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Constipation	5	2	40,00	3	60,00	7,16	7,16	NA	-	-	-	-	0,7879
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Constipation	171	29	16,96	142	83,04	NA	NA	NA	1,05	0,63	1,75	0,8604	0,7879
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Constipation	185	31	16,76	154	83,24	NA	NA	NA	-	-	-	-	0,7879
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	Constipation	48	11	22,92	37	77,08	NA	NA	NA	1,52	0,60	3,84	0,3722	0,2677
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	Constipation	47	8	17,02	39	82,98	NA	NA	NA	-	-	-	-	0,2677
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	Constipation	147	22	14,97	125	85,03	NA	NA	NA	0,82	0,47	1,44	0,4981	0,2677
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	Constipation	157	28	17,83	129	82,17	NA	NA	NA	-	-	-	-	0,2677
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	Constipation	98	18	18,37	80	81,63	NA	NA	NA	1,28	0,64	2,54	0,4824	0,2782
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	Constipation	104	15	14,42	89	85,58	NA	NA	NA	-	-	-	-	0,2782
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	Constipation	97	15	15,46	82	84,54	NA	NA	NA	0,75	0,39	1,47	0,4023	0,2782
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	Constipation	100	21	21,00	79	79,00	NA	35,75	NA	-	-	-	-	0,2782
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	Constipation	98	13	13,27	85	86,73	NA	NA	NA	0,70	0,35	1,39	0,3001	0,1846
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	Constipation	111	22	19,82	89	80,18	NA	35,75	NA	-	-	-	-	0,1846
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	Constipation	97	20	20,62	77	79,38	NA	NA	NA	1,34	0,68	2,66	0,3966	0,1846
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	Constipation	93	14	15,05	79	84,95	NA	NA	NA	-	-	-	-	0,1846
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	Constipation	61	14	22,95	47	77,05	NA	NA	NA	1,24	0,58	2,67	0,5804	0,5178
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	Constipation	62	14	22,58	48	77,42	NA	NA	NA	-	-	-	-	0,5178
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	Constipation	134	19	14,18	115	85,82	NA	NA	NA	0,90	0,48	1,66	0,7292	0,5178

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	Constipation	142	22	15,49	120	84,51	NA	NA	NA	-	-	-	-	0,5178
Patients with at least one AE	total	-	SVd Arm	Gastrointestinal disorders	Abdominal pain	195	10	5,13	185	94,87	NA	NA	NA	2,88	0,90	9,22	0,0630	NA
Patients with at least one AE	total	-	Vd Arm	Gastrointestinal disorders	Abdominal pain	204	4	1,96	200	98,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	80	18	22,50	62	77,50	NA	NA	NA	2,21	1,00	4,89	0,0465	0,1538
Patients with at least one AE	Gender	Female	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	91	11	12,09	80	87,91	NA	NA	NA	-	-	-	-	0,1538
Patients with at least one AE	Gender	Male	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	115	17	14,78	98	85,22	NA	NA	NA	1,03	0,52	2,03	0,9286	0,1538
Patients with at least one AE	Gender	Male	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	113	17	15,04	96	84,96	NA	NA	NA	-	-	-	-	0,1538
Patients with at least one AE	Age Group	<65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	86	19	22,09	67	77,91	NA	NA	NA	1,45	0,68	3,08	0,3368	0,7550
Patients with at least one AE	Age Group	<65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	75	12	16,00	63	84,00	NA	NA	NA	-	-	-	-	0,7550
Patients with at least one AE	Age Group	>=65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	109	16	14,68	93	85,32	NA	NA	NA	1,23	0,61	2,48	0,5689	0,7550
Patients with at least one AE	Age Group	>=65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	129	16	12,40	113	87,60	NA	NA	NA	-	-	-	-	0,7550
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	173	30	17,34	143	82,66	NA	NA	NA	1,38	0,79	2,41	0,2523	0,2431
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	174	22	12,64	152	87,36	NA	NA	NA	-	-	-	-	0,2431
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	12	3	25,00	9	75,00	NA	NA	NA	0,44	0,07	2,79	0,3695	0,2431
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,2431
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	163	29	17,79	134	82,21	NA	NA	NA	1,25	0,73	2,15	0,4177	0,6712
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	173	25	14,45	148	85,55	NA	NA	NA	-	-	-	-	0,6712
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	32	6	18,75	26	81,25	NA	NA	NA	1,74	0,41	7,36	0,4443	0,6712
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,6712
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	18	7	38,89	11	61,11	9,92	6,01	NA	1,39	0,36	5,42	0,6317	0,8141
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	17	5	29,41	12	70,59	NA	6,93	NA	-	-	-	-	0,8141
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	61	9	14,75	52	85,25	NA	18,99	NA	0,99	0,41	2,40	0,9756	0,8141
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	64	11	17,19	53	82,81	NA	17,45	NA	-	-	-	-	0,8141
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	47	3	6,38	44	93,62	NA	NA	NA	1,45	0,24	8,91	0,6844	0,8141

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,8141
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	69	16	23,19	53	76,81	NA	NA	NA	1,78	0,80	3,94	0,1489	0,8141
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	70	10	14,29	60	85,71	NA	NA	NA	-	-	-	-	0,8141
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	117	17	14,53	100	85,47	NA	NA	NA	1,23	0,61	2,48	0,5650	0,8845
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	136	15	11,03	121	88,97	NA	NA	NA	-	-	-	-	0,8845
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	78	18	23,08	60	76,92	NA	NA	NA	1,32	0,64	2,75	0,4504	0,8845
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	68	13	19,12	55	80,88	NA	NA	NA	-	-	-	-	0,8845
Patients with at least one AE	Race	Races other than White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	34	17	50,00	17	50,00	9,56	1,48	NA	1,96	0,91	4,21	0,0789	0,3055
Patients with at least one AE	Race	Races other than White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	42	14	33,33	28	66,67	17,45	16,85	NA	-	-	-	-	0,3055
Patients with at least one AE	Race	White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	161	18	11,18	143	88,82	NA	NA	NA	1,14	0,56	2,31	0,7220	0,3055
Patients with at least one AE	Race	White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	162	14	8,64	148	91,36	NA	NA	NA	-	-	-	-	0,3055
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	6	0	0,00	6	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	5	2	40,00	3	60,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	171	32	18,71	139	81,29	NA	NA	NA	1,39	0,82	2,34	0,2159	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	185	26	14,05	159	85,95	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	48	7	14,58	41	85,42	NA	NA	NA	1,70	0,49	5,87	0,4001	0,6934
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,6934
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	147	28	19,05	119	80,95	NA	NA	NA	1,29	0,75	2,23	0,3618	0,6934
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	157	24	15,29	133	84,71	NA	NA	NA	-	-	-	-	0,6934

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	98	18	18,37	80	81,63	NA	NA	NA	1,63	0,78	3,41	0,1852	0,4793
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	104	12	11,54	92	88,46	NA	NA	NA	-	-	-	-	0,4793
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	97	17	17,53	80	82,47	NA	NA	NA	1,14	0,57	2,26	0,7159	0,4793
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	100	16	16,00	84	84,00	NA	NA	NA	-	-	-	-	0,4793
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	98	17	17,35	81	82,65	NA	NA	NA	1,55	0,76	3,18	0,2230	0,4716
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	111	14	12,61	97	87,39	NA	NA	NA	-	-	-	-	0,4716
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	97	18	18,56	79	81,44	NA	22,90	NA	1,07	0,53	2,18	0,8444	0,4716
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	93	14	15,05	79	84,95	NA	NA	NA	-	-	-	-	0,4716
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	61	9	14,75	52	85,25	NA	NA	NA	1,74	0,56	5,44	0,3331	0,6597
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	62	6	9,68	56	90,32	NA	19,94	NA	-	-	-	-	0,6597
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	134	26	19,40	108	80,60	NA	NA	NA	1,31	0,74	2,32	0,3554	0,6597
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	142	22	15,49	120	84,51	NA	NA	NA	-	-	-	-	0,6597
Patients with at least one AE	total	-	SVd Arm	Gastrointestinal disorders	Constipation	195	33	16,92	162	83,08	NA	NA	NA	0,97	0,61	1,56	0,9082	NA
Patients with at least one AE	total	-	Vd Arm	Gastrointestinal disorders	Constipation	204	36	17,65	168	82,35	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	80	32	40,00	48	60,00	NA	7,85	NA	13,24	4,03	43,52	0,0000	0,3154
Patients with at least one AE	Gender	Female	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,3154
Patients with at least one AE	Gender	Male	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	115	38	33,04	77	66,96	NA	NA	NA	6,33	2,80	14,27	0,0000	0,3154
Patients with at least one AE	Gender	Male	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	113	7	6,19	106	93,81	NA	NA	NA	-	-	-	-	0,3154
Patients with at least one AE	Age Group	<65	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	86	29	33,72	57	66,28	NA	NA	NA	4,11	1,78	9,51	0,0004	0,0333
Patients with at least one AE	Age Group	<65	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	75	7	9,33	68	90,67	NA	NA	NA	-	-	-	-	0,0333

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	>=65	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	109	41	37,61	68	62,39	NA	11,53	NA	19,72	6,09	63,89	0,0000	0,0333
Patients with at least one AE	Age Group	>=65	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	0,0333
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	173	60	34,68	113	65,32	NA	NA	NA	8,86	4,23	18,58	0,0000	0,6180
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	0,6180
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	12	5	41,67	7	58,33	NA	1,64	NA	4,89	0,53	44,89	0,1286	0,6180
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,6180
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	163	55	33,74	108	66,26	NA	NA	NA	9,76	4,44	21,45	0,0000	0,3643
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	173	7	4,05	166	95,95	NA	NA	NA	-	-	-	-	0,3643
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	32	15	46,88	17	53,12	5,59	2,56	NA	4,92	1,41	17,18	0,0058	0,3643
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,3643
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	18	8	44,44	10	55,56	-	-	-	-	-	-	-	0,4357
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,4357
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	61	28	45,90	33	54,10	7,85	2,63	NA	11,88	3,59	39,36	0,0000	0,4357
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,4357
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	47	11	23,40	36	76,60	NA	NA	NA	10,15	1,31	78,82	0,0062	0,4357
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,4357
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	69	23	33,33	46	66,67	NA	NA	NA	4,65	1,89	11,46	0,0002	0,4357
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	70	6	8,57	64	91,43	NA	NA	NA	-	-	-	-	0,4357
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	117	40	34,19	77	65,81	NA	NA	NA	13,16	4,69	36,93	0,0000	0,2182
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	136	4	2,94	132	97,06	NA	NA	NA	-	-	-	-	0,2182
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	78	30	38,46	48	61,54	NA	4,63	NA	5,61	2,32	13,57	0,0000	0,2182
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	68	6	8,82	62	91,18	NA	NA	NA	-	-	-	-	0,2182

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	Races other than White	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	34	17	50,00	17	50,00	4,27	1,25	NA	4,39	1,70	11,33	0,0010	0,0439
Patients with at least one AE	Race	Races other than White	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	42	7	16,67	35	83,33	NA	21,52	NA	-	-	-	-	0,0439
Patients with at least one AE	Race	White	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	161	53	32,92	108	67,08	NA	NA	NA	20,57	6,41	65,95	0,0000	0,0439
Patients with at least one AE	Race	White	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	0,0439
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	171	55	32,16	116	67,84	NA	NA	NA	6,98	3,55	13,74	0,0000	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	185	10	5,41	175	94,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	48	19	39,58	29	60,42	NA	4,01	NA	11,48	2,66	49,49	0,0000	0,6617
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,6617
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	147	51	34,69	96	65,31	NA	NA	NA	7,96	3,77	16,79	0,0000	0,6617
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	157	8	5,10	149	94,90	NA	NA	NA	-	-	-	-	0,6617
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	98	35	35,71	63	64,29	NA	11,53	NA	6,22	2,76	14,03	0,0000	0,2530
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	104	7	6,73	97	93,27	NA	NA	NA	-	-	-	-	0,2530
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	97	35	36,08	62	63,92	NA	NA	NA	14,36	4,41	46,77	0,0000	0,2530
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,2530
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	98	36	36,73	62	63,27	NA	8,61	NA	6,53	3,01	14,18	0,0000	0,2441
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,2441
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	97	34	35,05	63	64,95	NA	NA	NA	17,15	4,11	71,49	0,0000	0,2441

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,2441
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	61	26	42,62	35	57,38	NA	3,48	NA	16,77	3,95	71,16	0,0000	0,2840
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,2840
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	134	44	32,84	90	67,16	NA	NA	NA	6,88	3,23	14,64	0,0000	0,2840
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	142	8	5,63	134	94,37	NA	NA	NA	-	-	-	-	0,2840
Patients with at least one AE	total	-	SVd Arm	Gastrointestinal disorders	Diarrhoea	195	66	33,85	129	66,15	30,03	16,26	NA	1,30	0,90	1,87	0,1651	NA
Patients with at least one AE	total	-	Vd Arm	Gastrointestinal disorders	Diarrhoea	204	53	25,98	151	74,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Gastrointestinal disorders	Diarrhoea	80	30	37,50	50	62,50	20,24	12,88	NA	1,71	0,95	3,07	0,0684	0,1970
Patients with at least one AE	Gender	Female	Vd Arm	Gastrointestinal disorders	Diarrhoea	91	22	24,18	69	75,82	NA	NA	NA	-	-	-	-	0,1970
Patients with at least one AE	Gender	Male	SVd Arm	Gastrointestinal disorders	Diarrhoea	115	36	31,30	79	68,70	30,03	14,92	NA	1,03	0,63	1,70	0,8920	0,1970
Patients with at least one AE	Gender	Male	Vd Arm	Gastrointestinal disorders	Diarrhoea	113	31	27,43	82	72,57	NA	18,79	NA	-	-	-	-	0,1970
Patients with at least one AE	Age Group	<65	SVd Arm	Gastrointestinal disorders	Diarrhoea	86	36	41,86	50	58,14	14,92	8,41	NA	2,11	1,13	3,94	0,0176	0,0470
Patients with at least one AE	Age Group	<65	Vd Arm	Gastrointestinal disorders	Diarrhoea	75	16	21,33	59	78,67	NA	NA	NA	-	-	-	-	0,0470
Patients with at least one AE	Age Group	>=65	SVd Arm	Gastrointestinal disorders	Diarrhoea	109	30	27,52	79	72,48	NA	30,03	NA	0,94	0,58	1,53	0,8115	0,0470
Patients with at least one AE	Age Group	>=65	Vd Arm	Gastrointestinal disorders	Diarrhoea	129	37	28,68	92	71,32	NA	18,79	NA	-	-	-	-	0,0470
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Diarrhoea	173	59	34,10	114	65,90	30,03	16,26	NA	1,35	0,91	2,02	0,1366	0,8770
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Diarrhoea	174	43	24,71	131	75,29	NA	NA	NA	-	-	-	-	0,8770
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Diarrhoea	12	5	41,67	7	58,33	6,31	3,75	NA	1,52	0,38	6,01	0,5514	0,8770
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Diarrhoea	16	6	37,50	10	62,50	12,65	4,40	NA	-	-	-	-	0,8770
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Diarrhoea	163	59	36,20	104	63,80	30,03	14,92	NA	1,28	0,87	1,90	0,2055	0,7305
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Diarrhoea	173	47	27,17	126	72,83	NA	NA	NA	-	-	-	-	0,7305
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Diarrhoea	32	7	21,88	25	78,12	NA	8,54	NA	1,61	0,47	5,47	0,4416	0,7305

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Diarrhoea	31	6	19,35	25	80,65	NA	NA	NA	-	-	-	-	0,7305
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	Diarrhoea	18	7	38,89	11	61,11	21,39	3,32	NA	0,80	0,23	2,83	0,7318	0,3070
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	Diarrhoea	17	8	47,06	9	52,94	4,80	1,87	NA	-	-	-	-	0,3070
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	Diarrhoea	61	26	42,62	35	57,38	14,36	4,67	NA	1,65	0,89	3,07	0,1106	0,3070
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	Diarrhoea	64	17	26,56	47	73,44	NA	12,29	NA	-	-	-	-	0,3070
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	Diarrhoea	47	9	19,15	38	80,85	NA	30,03	NA	0,66	0,27	1,64	0,3692	0,3070
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	Diarrhoea	53	11	20,75	42	79,25	NA	18,79	NA	-	-	-	-	0,3070
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	Diarrhoea	69	24	34,78	45	65,22	33,77	14,92	NA	1,58	0,83	2,99	0,1612	0,3070
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	Diarrhoea	70	17	24,29	53	75,71	NA	NA	NA	-	-	-	-	0,3070
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	Diarrhoea	117	38	32,48	79	67,52	30,03	20,24	NA	1,12	0,70	1,77	0,6423	0,3659
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	Diarrhoea	136	36	26,47	100	73,53	NA	18,79	NA	-	-	-	-	0,3659
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	Diarrhoea	78	28	35,90	50	64,10	16,26	12,19	NA	1,60	0,86	2,97	0,1377	0,3659
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	Diarrhoea	68	17	25,00	51	75,00	NA	NA	NA	-	-	-	-	0,3659
Patients with at least one AE	Race	Races other than White	SVd Arm	Gastrointestinal disorders	Diarrhoea	34	17	50,00	17	50,00	6,31	1,71	NA	1,55	0,74	3,23	0,2380	0,5097
Patients with at least one AE	Race	Races other than White	Vd Arm	Gastrointestinal disorders	Diarrhoea	42	15	35,71	27	64,29	NA	8,90	NA	-	-	-	-	0,5097
Patients with at least one AE	Race	White	SVd Arm	Gastrointestinal disorders	Diarrhoea	161	49	30,43	112	69,57	33,77	20,24	NA	1,16	0,75	1,80	0,4912	0,5097
Patients with at least one AE	Race	White	Vd Arm	Gastrointestinal disorders	Diarrhoea	162	38	23,46	124	76,54	NA	NA	NA	-	-	-	-	0,5097
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Diarrhoea	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Diarrhoea	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Diarrhoea	171	56	32,75	115	67,25	30,03	14,92	NA	1,24	0,84	1,83	0,2884	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Diarrhoea	185	49	26,49	136	73,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	Diarrhoea	48	15	31,25	33	68,75	33,77	14,92	NA	1,36	0,59	3,13	0,4634	0,8946
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	Diarrhoea	47	10	21,28	37	78,72	NA	NA	NA	-	-	-	-	0,8946
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	Diarrhoea	147	51	34,69	96	65,31	21,39	14,36	NA	1,28	0,85	1,93	0,2356	0,8946
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	Diarrhoea	157	43	27,39	114	72,61	NA	18,79	NA	-	-	-	-	0,8946
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	Diarrhoea	98	34	34,69	64	65,31	21,39	10,15	NA	1,28	0,77	2,12	0,3443	0,9304
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	Diarrhoea	104	28	26,92	76	73,08	NA	NA	NA	-	-	-	-	0,9304
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	Diarrhoea	97	32	32,99	65	67,01	33,77	16,26	NA	1,32	0,77	2,25	0,3078	0,9304
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	Diarrhoea	100	25	25,00	75	75,00	NA	18,79	NA	-	-	-	-	0,9304
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	Diarrhoea	98	35	35,71	63	64,29	30,03	16,26	NA	1,17	0,72	1,91	0,5224	0,5227
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	Diarrhoea	111	34	30,63	77	69,37	NA	12,65	NA	-	-	-	-	0,5227
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	Diarrhoea	97	31	31,96	66	68,04	NA	14,36	NA	1,50	0,84	2,67	0,1658	0,5227
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	Diarrhoea	93	19	20,43	74	79,57	NA	NA	NA	-	-	-	-	0,5227
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	Diarrhoea	61	20	32,79	41	67,21	33,77	14,36	NA	1,42	0,66	3,06	0,3665	0,7620
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	Diarrhoea	62	13	20,97	49	79,03	NA	NA	NA	-	-	-	-	0,7620
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	Diarrhoea	134	46	34,33	88	65,67	21,39	16,26	NA	1,24	0,81	1,90	0,3211	0,7620
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	Diarrhoea	142	40	28,17	102	71,83	NA	18,79	NA	-	-	-	-	0,7620
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Gastrointestinal disorders	Diarrhoea	195	14	7,18	181	92,82	NA	NA	NA	13,31	1,74	101,84	0,0012	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Gastrointestinal disorders	Diarrhoea	204	1	0,49	203	99,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Gastrointestinal disorders	Diarrhoea	80	7	8,75	73	91,25	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Gastrointestinal disorders	Diarrhoea	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Gastrointestinal disorders	Diarrhoea	115	7	6,09	108	93,91	NA	NA	NA	6,67	0,80	55,43	0,0445	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Gastrointestinal disorders	Diarrhoea	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Gastrointestinal disorders	Diarrhoea	86	7	8,14	79	91,86	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Gastrointestinal disorders	Diarrhoea	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Gastrointestinal disorders	Diarrhoea	109	7	6,42	102	93,58	NA	NA	NA	8,51	1,04	69,82	0,0172	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Gastrointestinal disorders	Diarrhoea	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Diarrhoea	173	13	7,51	160	92,49	NA	NA	NA	11,75	1,53	90,44	0,0026	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Diarrhoea	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Diarrhoea	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Diarrhoea	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Diarrhoea	163	13	7,98	150	92,02	NA	NA	NA	12,83	1,67	98,80	0,0015	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Diarrhoea	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Diarrhoea	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Diarrhoea	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	Diarrhoea	18	2	11,11	16	88,89	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	Diarrhoea	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	Diarrhoea	61	4	6,56	57	93,44	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	Diarrhoea	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	Diarrhoea	47	1	2,13	46	97,87	NA	NA	NA	1,11	0,07	17,89	0,9437	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	Diarrhoea	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	Diarrhoea	69	7	10,14	62	89,86	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	Diarrhoea	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	Diarrhoea	117	5	4,27	112	95,73	NA	NA	NA	5,30	0,61	46,32	0,0940	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	Diarrhoea	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	Diarrhoea	78	9	11,54	69	88,46	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	Diarrhoea	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Gastrointestinal disorders	Diarrhoea	34	4	11,76	30	88,24	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Gastrointestinal disorders	Diarrhoea	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Gastrointestinal disorders	Diarrhoea	161	10	6,21	151	93,79	NA	NA	NA	8,48	1,07	67,45	0,0159	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Gastrointestinal disorders	Diarrhoea	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Diarrhoea	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Diarrhoea	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Diarrhoea	171	14	8,19	157	91,81	NA	NA	NA	13,87	1,81	106,20	0,0009	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Diarrhoea	185	1	0,54	184	99,46	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	Diarrhoea	48	4	8,33	44	91,67	NA	33,77	NA	2,90	0,30	27,90	0,3353	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	Diarrhoea	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	Diarrhoea	147	10	6,80	137	93,20	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	Diarrhoea	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	Diarrhoea	98	9	9,18	89	90,82	NA	NA	NA	9,28	1,18	73,33	0,0100	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	Diarrhoea	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	Diarrhoea	97	5	5,15	92	94,85	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	Diarrhoea	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	Diarrhoea	98	9	9,18	89	90,82	NA	NA	NA	8,86	1,10	71,29	0,0136	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	Diarrhoea	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	Diarrhoea	97	5	5,15	92	94,85	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	Diarrhoea	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	Diarrhoea	61	4	6,56	57	93,44	NA	NA	NA	2,90	0,30	27,90	0,3353	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	Diarrhoea	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	Diarrhoea	134	10	7,46	124	92,54	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	Diarrhoea	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Gastrointestinal disorders	Nausea	195	98	50,26	97	49,74	4,60	2,56	NA	6,60	4,11	10,60	0,0000	NA
Patients with at least one AE	total	-	Vd Arm	Gastrointestinal disorders	Nausea	204	21	10,29	183	89,71	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Nervous system disorders	Dizziness	80	9	11,25	71	88,75	NA	NA	NA	3,26	0,87	12,16	0,0633	0,6558
Patients with at least one AE	Gender	Female	Vd Arm	Nervous system disorders	Dizziness	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,6558
Patients with at least one AE	Gender	Male	SVd Arm	Nervous system disorders	Dizziness	115	15	13,04	100	86,96	NA	NA	NA	2,27	0,92	5,58	0,0675	0,6558
Patients with at least one AE	Gender	Male	Vd Arm	Nervous system disorders	Dizziness	113	7	6,19	106	93,81	NA	NA	NA	-	-	-	-	0,6558
Patients with at least one AE	Age Group	<65	SVd Arm	Nervous system disorders	Dizziness	86	8	9,30	78	90,70	NA	NA	NA	1,21	0,39	3,77	0,7394	0,0814
Patients with at least one AE	Age Group	<65	Vd Arm	Nervous system disorders	Dizziness	75	5	6,67	70	93,33	NA	NA	NA	-	-	-	-	0,0814
Patients with at least one AE	Age Group	>=65	SVd Arm	Nervous system disorders	Dizziness	109	16	14,68	93	85,32	NA	NA	NA	4,68	1,70	12,91	0,0011	0,0814
Patients with at least one AE	Age Group	>=65	Vd Arm	Nervous system disorders	Dizziness	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,0814
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Dizziness	173	21	12,14	152	87,86	NA	NA	NA	3,21	1,36	7,56	0,0050	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Dizziness	174	7	4,02	167	95,98	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	Dizziness	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	Dizziness	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Dizziness	163	23	14,11	140	85,89	NA	NA	NA	3,11	1,39	6,98	0,0036	0,1355

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Dizziness	173	8	4,62	165	95,38	NA	NA	NA	-	-	-	-	0,1355
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	Dizziness	32	1	3,12	31	96,88	NA	NA	NA	0,43	0,04	5,10	0,4913	0,1355
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	Dizziness	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,1355
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	Dizziness	18	5	27,78	13	72,22	NA	3,25	NA	1,66	0,29	9,42	0,5644	0,1773
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	Dizziness	17	2	11,76	15	88,24	21,75	NA	NA	-	-	-	-	0,1773
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	Dizziness	61	15	24,59	46	75,41	NA	15,44	NA	6,04	1,71	21,33	0,0016	0,1773
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	Dizziness	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,1773
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	Dizziness	47	0	0,00	47	100,00	-	-	-	-	-	-	-	0,1773
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	Dizziness	53	1	1,89	52	98,11	-	-	-	-	-	-	-	0,1773
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	Dizziness	69	4	5,80	65	94,20	NA	NA	NA	1,09	0,27	4,39	0,9046	0,1773
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	Dizziness	70	4	5,71	66	94,29	NA	NA	NA	-	-	-	-	0,1773
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	Dizziness	117	16	13,68	101	86,32	NA	NA	NA	2,59	1,06	6,32	0,0309	0,9814
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	Dizziness	136	7	5,15	129	94,85	NA	NA	NA	-	-	-	-	0,9814
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	Dizziness	78	8	10,26	70	89,74	NA	NA	NA	2,64	0,70	9,99	0,1385	0,9814
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	Dizziness	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,9814
Patients with at least one AE	Race	Races other than White	SVd Arm	Nervous system disorders	Dizziness	34	4	11,76	30	88,24	NA	NA	NA	4,31	0,78	23,74	0,0678	0,7294
Patients with at least one AE	Race	Races other than White	Vd Arm	Nervous system disorders	Dizziness	42	3	7,14	39	92,86	NA	NA	NA	-	-	-	-	0,7294
Patients with at least one AE	Race	White	SVd Arm	Nervous system disorders	Dizziness	161	20	12,42	141	87,58	NA	NA	NA	3,08	1,30	7,30	0,0073	0,7294
Patients with at least one AE	Race	White	Vd Arm	Nervous system disorders	Dizziness	162	7	4,32	155	95,68	NA	NA	NA	-	-	-	-	0,7294
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Dizziness	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Dizziness	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Dizziness	171	21	12,28	150	87,72	NA	NA	NA	2,33	1,10	4,97	0,0237	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Dizziness	185	10	5,41	175	94,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Nervous system disorders	Dizziness	48	4	8,33	44	91,67	NA	NA	NA	2,15	0,39	11,75	0,3677	0,8313
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Nervous system disorders	Dizziness	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,8313
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Nervous system disorders	Dizziness	147	20	13,61	127	86,39	NA	NA	NA	2,63	1,16	5,99	0,0164	0,8313
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Nervous system disorders	Dizziness	157	8	5,10	149	94,90	NA	NA	NA	-	-	-	-	0,8313
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	Dizziness	98	9	9,18	89	90,82	NA	NA	NA	2,30	0,71	7,48	0,1550	0,8354
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	Dizziness	104	4	3,85	100	96,15	NA	NA	NA	-	-	-	-	0,8354
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	Dizziness	97	15	15,46	82	84,54	NA	NA	NA	2,70	1,04	6,97	0,0328	0,8354
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	Dizziness	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,8354
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	Dizziness	98	12	12,24	86	87,76	NA	NA	NA	3,79	1,22	11,79	0,0136	0,3484
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	Dizziness	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,3484
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	Dizziness	97	12	12,37	85	87,63	NA	NA	NA	1,85	0,69	4,94	0,2145	0,3484
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	Dizziness	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,3484
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	Dizziness	61	7	11,48	54	88,52	NA	NA	NA	2,88	0,74	11,22	0,1121	0,8576
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	Dizziness	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,8576
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	Dizziness	134	17	12,69	117	87,31	NA	NA	NA	2,48	1,03	5,99	0,0368	0,8576
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	Dizziness	142	7	4,93	135	95,07	NA	NA	NA	-	-	-	-	0,8576

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	total	-	SVd Arm	Gastrointestinal disorders	Vomiting	195	40	20,51	155	79,49	NA	NA	NA	4,57	2,27	9,19	0,0000	NA
Patients with at least one AE	total	-	Vd Arm	Gastrointestinal disorders	Vomiting	204	10	4,90	194	95,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Nervous system disorders	Dysgeusia	80	5	6,25	75	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Female	Vd Arm	Nervous system disorders	Dysgeusia	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Male	SVd Arm	Nervous system disorders	Dysgeusia	115	8	6,96	107	93,04	NA	NA	NA	8,60	1,07	69,08	0,0152	NA
Patients with at least one AE	Gender	Male	Vd Arm	Nervous system disorders	Dysgeusia	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Age Group	<65	SVd Arm	Nervous system disorders	Dysgeusia	86	6	6,98	80	93,02	-	-	-	-	-	-	-	NA
Patients with at least one AE	Age Group	<65	Vd Arm	Nervous system disorders	Dysgeusia	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Age Group	>=65	SVd Arm	Nervous system disorders	Dysgeusia	109	7	6,42	102	93,58	NA	NA	NA	8,39	1,02	68,80	0,0182	NA
Patients with at least one AE	Age Group	>=65	Vd Arm	Nervous system disorders	Dysgeusia	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Dysgeusia	173	11	6,36	162	93,64	NA	NA	NA	11,97	1,54	93,00	0,0025	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Dysgeusia	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	Dysgeusia	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	Dysgeusia	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Dysgeusia	163	12	7,36	151	92,64	NA	NA	NA	13,03	1,69	100,25	0,0014	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Dysgeusia	173	1	0,58	172	99,42	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	Dysgeusia	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	Dysgeusia	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	Dysgeusia	18	4	22,22	14	77,78	NA	5,55	NA	4,65	0,48	44,60	0,1504	NA
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	Dysgeusia	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	Dysgeusia	61	5	8,20	56	91,80	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	Dysgeusia	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	Dysgeusia	47	2	4,26	45	95,74	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	Dysgeusia	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	Dysgeusia	69	2	2,90	67	97,10	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	Dysgeusia	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	Dysgeusia	117	8	6,84	109	93,16	NA	NA	NA	9,40	1,17	75,45	0,0102	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	Dysgeusia	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	Dysgeusia	78	5	6,41	73	93,59	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	Dysgeusia	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	SVd Arm	Nervous system disorders	Dysgeusia	34	3	8,82	31	91,18	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Nervous system disorders	Dysgeusia	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Nervous system disorders	Dysgeusia	161	10	6,21	151	93,79	NA	NA	NA	9,68	1,23	75,98	0,0083	NA
Patients with at least one AE	Race	White	Vd Arm	Nervous system disorders	Dysgeusia	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Dysgeusia	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Dysgeusia	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Dysgeusia	171	13	7,60	158	92,40	NA	NA	NA	14,17	1,85	108,48	0,0008	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Dysgeusia	185	1	0,54	184	99,46	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Nervous system disorders	Dysgeusia	48	1	2,08	47	97,92	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Nervous system disorders	Dysgeusia	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Nervous system disorders	Dysgeusia	147	12	8,16	135	91,84	NA	NA	NA	12,81	1,66	98,63	0,0015	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Nervous system disorders	Dysgeusia	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	Dysgeusia	98	8	8,16	90	91,84	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	Dysgeusia	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	Dysgeusia	97	5	5,15	92	94,85	NA	NA	NA	5,55	0,65	47,64	0,0783	NA
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	Dysgeusia	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	Dysgeusia	98	5	5,10	93	94,90	NA	NA	NA	6,03	0,70	51,68	0,0620	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	Dysgeusia	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	Dysgeusia	97	8	8,25	89	91,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	Dysgeusia	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	Dysgeusia	61	2	3,28	59	96,72	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	Dysgeusia	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	Dysgeusia	134	11	8,21	123	91,79	NA	NA	NA	11,67	1,50	90,50	0,0029	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	Dysgeusia	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Gastrointestinal disorders	-	195	137	70,26	58	29,74	0,59	0,26	1,61	2,18	1,67	2,85	0,0000	NA
Patients with at least one AE	total	-	Vd Arm	Gastrointestinal disorders	-	204	93	45,59	111	54,41	14,62	4,40	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	80	3	3,75	77	96,25	NA	NA	NA	2,87	0,30	27,92	0,3424	0,3888
Patients with at least one AE	Gender	Female	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,3888
Patients with at least one AE	Gender	Male	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	115	7	6,09	108	93,91	NA	NA	NA	0,96	0,34	2,68	0,9336	0,3888
Patients with at least one AE	Gender	Male	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	113	8	7,08	105	92,92	NA	33,45	NA	-	-	-	-	0,3888
Patients with at least one AE	Age Group	<65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	86	6	6,98	80	93,02	NA	NA	NA	1,80	0,43	7,43	0,4130	0,4702
Patients with at least one AE	Age Group	<65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,4702
Patients with at least one AE	Age Group	>=65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	109	4	3,67	105	96,33	NA	NA	NA	0,89	0,25	3,20	0,8551	0,4702

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	>=65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	0,4702
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	173	10	5,78	163	94,22	NA	NA	NA	1,44	0,56	3,71	0,4461	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	163	10	6,13	153	93,87	NA	NA	NA	1,23	0,50	3,06	0,6519	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	173	9	5,20	164	94,80	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	18	1	5,56	17	94,44	NA	NA	NA	1,41	0,08	23,57	0,8084	0,4345
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,4345
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	61	5	8,20	56	91,80	NA	NA	NA	2,02	0,47	8,66	0,3370	0,4345
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,4345
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	47	2	4,26	45	95,74	-	-	-	-	-	-	-	0,4345
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,4345
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	69	2	2,90	67	97,10	NA	NA	NA	0,47	0,09	2,56	0,3689	0,4345
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	70	5	7,14	65	92,86	NA	33,45	NA	-	-	-	-	0,4345
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	117	6	5,13	111	94,87	NA	NA	NA	2,29	0,56	9,41	0,2395	0,2097
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	136	3	2,21	133	97,79	NA	NA	NA	-	-	-	-	0,2097
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	78	4	5,13	74	94,87	NA	NA	NA	0,66	0,18	2,48	0,5399	0,2097
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	68	6	8,82	62	91,18	NA	33,45	NA	-	-	-	-	0,2097
Patients with at least one AE	Race	Races other than White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	34	2	5,88	32	94,12	NA	NA	NA	0,19	0,02	1,78	0,1124	0,0435

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	Races other than White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	42	6	14,29	36	85,71	NA	33,45	NA	-	-	-	-	0,0435
Patients with at least one AE	Race	White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	161	8	4,97	153	95,03	NA	NA	NA	2,79	0,73	10,67	0,1183	0,0435
Patients with at least one AE	Race	White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	0,0435
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	171	9	5,26	162	94,74	NA	NA	NA	1,15	0,45	2,93	0,7641	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	185	9	4,86	176	95,14	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	48	1	2,08	47	97,92	NA	NA	NA	0,32	0,03	3,11	0,3019	0,1794
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,1794
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	147	9	6,12	138	93,88	NA	NA	NA	1,78	0,63	5,06	0,2732	0,1794
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	157	6	3,82	151	96,18	NA	NA	NA	-	-	-	-	0,1794
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	98	4	4,08	94	95,92	NA	NA	NA	0,89	0,23	3,36	0,8613	0,4830
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,4830
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	97	6	6,19	91	93,81	NA	NA	NA	1,72	0,48	6,12	0,3994	0,4830
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,4830
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	98	6	6,12	92	93,88	NA	NA	NA	1,22	0,41	3,66	0,7244	0,6704
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	111	7	6,31	104	93,69	NA	NA	NA	-	-	-	-	0,6704
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	97	4	4,12	93	95,88	NA	NA	NA	1,89	0,34	10,50	0,4571	0,6704
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,6704

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	61	1	1,64	60	98,36	NA	NA	NA	0,32	0,03	3,11	0,3019	0,1786
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,1786
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	134	9	6,72	125	93,28	NA	NA	NA	1,79	0,62	5,16	0,2733	0,1786
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	142	6	4,23	136	95,77	NA	NA	NA	-	-	-	-	0,1786
Patients with at least one AE	total	-	SVd Arm	General disorders and administration site conditions	Asthenia	195	49	25,13	146	74,87	NA	NA	NA	1,96	1,22	3,16	0,0049	NA
Patients with at least one AE	total	-	Vd Arm	General disorders and administration site conditions	Asthenia	204	27	13,24	177	86,76	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	80	11	13,75	69	86,25	NA	NA	NA	1,30	0,53	3,21	0,5690	0,0460
Patients with at least one AE	Gender	Female	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	91	10	10,99	81	89,01	NA	NA	NA	-	-	-	-	0,0460
Patients with at least one AE	Gender	Male	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	115	8	6,96	107	93,04	NA	41,07	NA	0,36	0,15	0,87	0,0174	0,0460
Patients with at least one AE	Gender	Male	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	113	18	15,93	95	84,07	NA	NA	NA	-	-	-	-	0,0460
Patients with at least one AE	Age Group	<65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	86	9	10,47	77	89,53	NA	41,07	NA	0,40	0,16	0,99	0,0416	0,2741
Patients with at least one AE	Age Group	<65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	75	12	16,00	63	84,00	NA	NA	NA	-	-	-	-	0,2741
Patients with at least one AE	Age Group	>=65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	109	10	9,17	99	90,83	NA	NA	NA	0,79	0,35	1,75	0,5537	0,2741
Patients with at least one AE	Age Group	>=65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	129	16	12,40	113	87,60	NA	NA	NA	-	-	-	-	0,2741
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	173	17	9,83	156	90,17	NA	NA	NA	0,66	0,35	1,22	0,1832	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	174	25	14,37	149	85,63	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	16	1	6,25	15	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	163	16	9,82	147	90,18	NA	NA	NA	0,62	0,33	1,17	0,1377	0,5077
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	173	26	15,03	147	84,97	NA	NA	NA	-	-	-	-	0,5077
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	32	3	9,38	29	90,62	41,07	NA	NA	0,27	0,02	3,08	0,2591	0,5077

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,5077
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	18	1	5,56	17	94,44	NA	NA	NA	0,45	0,04	5,02	0,5079	0,7455
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	17	3	17,65	14	82,35	NA	10,61	NA	-	-	-	-	0,7455
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	61	10	16,39	51	83,61	NA	NA	NA	0,72	0,32	1,64	0,4338	0,7455
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	64	14	21,88	50	78,12	NA	NA	NA	-	-	-	-	0,7455
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	47	2	4,26	45	95,74	-	-	-	-	-	-	-	0,7455
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,7455
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	69	6	8,70	63	91,30	41,07	41,07	NA	0,44	0,15	1,27	0,1166	0,7455
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	70	11	15,71	59	84,29	NA	NA	NA	-	-	-	-	0,7455
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	117	10	8,55	107	91,45	NA	NA	NA	0,70	0,31	1,58	0,3849	0,6158
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	136	15	11,03	121	88,97	NA	NA	NA	-	-	-	-	0,6158
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	78	9	11,54	69	88,46	41,07	41,07	NA	0,51	0,21	1,25	0,1342	0,6158
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	68	13	19,12	55	80,88	NA	NA	NA	-	-	-	-	0,6158
Patients with at least one AE	Race	Races other than White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	34	7	20,59	27	79,41	41,07	NA	NA	0,88	0,33	2,39	0,8056	0,7403
Patients with at least one AE	Race	Races other than White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	42	12	28,57	30	71,43	NA	17,77	NA	-	-	-	-	0,7403
Patients with at least one AE	Race	White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	161	12	7,45	149	92,55	NA	NA	NA	0,71	0,33	1,53	0,3837	0,7403
Patients with at least one AE	Race	White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	162	16	9,88	146	90,12	NA	NA	NA	-	-	-	-	0,7403
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	171	18	10,53	153	89,47	NA	NA	NA	0,75	0,40	1,40	0,3600	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	185	23	12,43	162	87,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	48	3	6,25	45	93,75	NA	NA	NA	0,93	0,19	4,63	0,9312	0,6088
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,6088
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	147	16	10,88	131	89,12	NA	41,07	NA	0,59	0,31	1,13	0,1089	0,6088
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	157	25	15,92	132	84,08	NA	NA	NA	-	-	-	-	0,6088
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	98	8	8,16	90	91,84	NA	NA	NA	0,50	0,21	1,19	0,1095	0,4556
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	104	15	14,42	89	85,58	NA	NA	NA	-	-	-	-	0,4556
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	97	11	11,34	86	88,66	NA	41,07	NA	0,79	0,34	1,81	0,5784	0,4556
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	100	13	13,00	87	87,00	NA	NA	NA	-	-	-	-	0,4556
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	98	10	10,20	88	89,80	NA	41,07	NA	0,68	0,30	1,57	0,3691	0,7504
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	111	15	13,51	96	86,49	NA	NA	NA	-	-	-	-	0,7504
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	97	9	9,28	88	90,72	NA	NA	NA	0,56	0,24	1,33	0,1858	0,7504
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	93	13	13,98	80	86,02	NA	NA	NA	-	-	-	-	0,7504
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	61	4	6,56	57	93,44	NA	NA	NA	0,73	0,19	2,79	0,6482	0,7915
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,7915
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	134	15	11,19	119	88,81	NA	41,07	NA	0,60	0,31	1,17	0,1314	0,7915
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	142	23	16,20	119	83,80	NA	NA	NA	-	-	-	-	0,7915
Patients with at least one AE	total	-	SVd Arm	General disorders and administration site conditions	Fatigue	195	82	42,05	113	57,95	NA	6,77	NA	2,80	1,90	4,14	0,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	total	-	Vd Arm	General disorders and administration site conditions	Fatigue	204	37	18,14	167	81,86	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	80	5	6,25	75	93,75	NA	NA	NA	4,80	0,55	41,73	0,1174	0,7087
Patients with at least one AE	Gender	Female	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,7087
Patients with at least one AE	Gender	Male	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	115	6	5,22	109	94,78	NA	NA	NA	2,87	0,57	14,38	0,1791	0,7087
Patients with at least one AE	Gender	Male	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,7087
Patients with at least one AE	Age Group	<65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	86	5	5,81	81	94,19	-	-	-	-	-	-	-	NA
Patients with at least one AE	Age Group	<65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Age Group	>=65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	109	6	5,50	103	94,50	NA	NA	NA	2,34	0,57	9,54	0,2241	NA
Patients with at least one AE	Age Group	>=65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	173	10	5,78	163	94,22	NA	NA	NA	3,34	0,90	12,31	0,0558	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	163	9	5,52	154	94,48	NA	NA	NA	2,97	0,80	11,03	0,0885	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	61	3	4,92	58	95,08	NA	NA	NA	1,06	0,21	5,27	0,9412	NA
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	47	3	6,38	44	93,62	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	69	4	5,80	65	94,20	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	117	6	5,13	111	94,87	NA	NA	NA	2,19	0,53	9,04	0,2656	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	136	3	2,21	133	97,79	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	78	5	6,41	73	93,59	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	161	10	6,21	151	93,79	NA	NA	NA	3,25	0,89	11,91	0,0606	NA
Patients with at least one AE	Race	White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	171	10	5,85	161	94,15	NA	NA	NA	5,28	1,15	24,22	0,0170	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	48	5	10,42	43	89,58	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	147	6	4,08	141	95,92	NA	NA	NA	2,17	0,54	8,72	0,2613	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	157	3	1,91	154	98,09	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	98	5	5,10	93	94,90	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	97	6	6,19	91	93,81	NA	NA	NA	1,97	0,49	7,95	0,3340	NA
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	98	5	5,10	93	94,90	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	97	6	6,19	91	93,81	NA	NA	NA	1,79	0,45	7,16	0,4064	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	61	5	8,20	56	91,80	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	134	6	4,48	128	95,52	NA	NA	NA	2,12	0,53	8,51	0,2776	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	142	3	2,11	139	97,89	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	General disorders and administration site conditions	Oedema peripheral	195	23	11,79	172	88,21	NA	NA	NA	0,82	0,47	1,42	0,4771	NA
Patients with at least one AE	total	-	Vd Arm	General disorders and administration site conditions	Oedema peripheral	204	29	14,22	175	85,78	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Injury, poisoning and procedural complications	Fall	80	2	2,50	78	97,50	NA	NA	NA	0,97	0,13	7,26	0,9751	0,7531
Patients with at least one AE	Gender	Female	Vd Arm	Injury, poisoning and procedural complications	Fall	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,7531
Patients with at least one AE	Gender	Male	SVd Arm	Injury, poisoning and procedural complications	Fall	115	9	7,83	106	92,17	NA	NA	NA	1,39	0,49	3,95	0,5307	0,7531
Patients with at least one AE	Gender	Male	Vd Arm	Injury, poisoning and procedural complications	Fall	113	6	5,31	107	94,69	NA	NA	NA	-	-	-	-	0,7531
Patients with at least one AE	Age Group	<65	SVd Arm	Injury, poisoning and procedural complications	Fall	86	3	3,49	83	96,51	NA	NA	NA	0,78	0,16	3,90	0,7600	0,3568

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	<65	Vd Arm	Injury, poisoning and procedural complications	Fall	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,3568
Patients with at least one AE	Age Group	>=65	SVd Arm	Injury, poisoning and procedural complications	Fall	109	8	7,34	101	92,66	NA	33,58	NA	1,96	0,64	6,06	0,2327	0,3568
Patients with at least one AE	Age Group	>=65	Vd Arm	Injury, poisoning and procedural complications	Fall	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,3568
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	Fall	173	11	6,36	162	93,64	NA	NA	NA	1,37	0,55	3,42	0,5024	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	Fall	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	Fall	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	Fall	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	Fall	163	11	6,75	152	93,25	NA	NA	NA	1,39	0,55	3,46	0,4830	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	Fall	173	8	4,62	165	95,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	Fall	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	Fall	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Injury, poisoning and procedural complications	Fall	18	3	16,67	15	83,33	NA	12,85	NA	0,62	0,08	4,61	0,6410	0,7735
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Injury, poisoning and procedural complications	Fall	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,7735
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Injury, poisoning and procedural complications	Fall	61	7	11,48	54	88,52	NA	NA	NA	1,45	0,45	4,60	0,5309	0,7735
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Injury, poisoning and procedural complications	Fall	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,7735
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Injury, poisoning and procedural complications	Fall	47	1	2,13	46	97,87	NA	33,58	NA	1,04	0,07	16,65	0,9774	0,7735

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Injury, poisoning and procedural complications	Fall	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,7735
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Injury, poisoning and procedural complications	Fall	69	0	0,00	69	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,7735
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Injury, poisoning and procedural complications	Fall	70	0	0,00	70	100,00	NA	NA	NA	-	-	-	-	0,7735
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Injury, poisoning and procedural complications	Fall	117	11	9,40	106	90,60	NA	NA	NA	1,46	0,58	3,64	0,4152	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Injury, poisoning and procedural complications	Fall	136	8	5,88	128	94,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Injury, poisoning and procedural complications	Fall	78	0	0,00	78	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Injury, poisoning and procedural complications	Fall	68	0	0,00	68	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	SVd Arm	Injury, poisoning and procedural complications	Fall	34	2	5,88	32	94,12	NA	NA	NA	4,52	0,41	50,24	0,1790	0,3935
Patients with at least one AE	Race	Races other than White	Vd Arm	Injury, poisoning and procedural complications	Fall	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,3935
Patients with at least one AE	Race	White	SVd Arm	Injury, poisoning and procedural complications	Fall	161	9	5,59	152	94,41	NA	NA	NA	1,44	0,51	4,09	0,4905	0,3935
Patients with at least one AE	Race	White	Vd Arm	Injury, poisoning and procedural complications	Fall	162	6	3,70	156	96,30	NA	NA	NA	-	-	-	-	0,3935
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	Fall	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	Fall	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	Fall	171	10	5,85	161	94,15	NA	NA	NA	1,31	0,51	3,37	0,5770	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	Fall	185	8	4,32	177	95,68	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Injury, poisoning and procedural complications	Fall	48	1	2,08	47	97,92	NA	NA	NA	0,59	0,05	6,75	0,6702	0,4637
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Injury, poisoning and procedural complications	Fall	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,4637
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Injury, poisoning and procedural complications	Fall	147	10	6,80	137	93,20	NA	NA	NA	1,59	0,57	4,39	0,3682	0,4637
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Injury, poisoning and procedural complications	Fall	157	6	3,82	151	96,18	NA	NA	NA	-	-	-	-	0,4637
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Injury, poisoning and procedural complications	Fall	98	3	3,06	95	96,94	NA	NA	NA	0,47	0,12	1,87	0,2718	0,0384
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Injury, poisoning and procedural complications	Fall	104	6	5,77	98	94,23	NA	NA	NA	-	-	-	-	0,0384
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Injury, poisoning and procedural complications	Fall	97	8	8,25	89	91,75	NA	NA	NA	4,25	0,89	20,29	0,0490	0,0384
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Injury, poisoning and procedural complications	Fall	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,0384
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Injury, poisoning and procedural complications	Fall	98	6	6,12	92	93,88	NA	NA	NA	1,76	0,49	6,26	0,3765	0,4575
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Injury, poisoning and procedural complications	Fall	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,4575
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Injury, poisoning and procedural complications	Fall	97	5	5,15	92	94,85	NA	33,58	NA	0,86	0,21	3,46	0,8343	0,4575
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Injury, poisoning and procedural complications	Fall	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,4575
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Injury, poisoning and procedural complications	Fall	61	2	3,28	59	96,72	NA	NA	NA	1,15	0,16	8,40	0,8882	0,8633
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Injury, poisoning and procedural complications	Fall	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,8633
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Injury, poisoning and procedural complications	Fall	134	9	6,72	125	93,28	NA	33,58	NA	1,40	0,50	3,96	0,5197	0,8633
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Injury, poisoning and procedural complications	Fall	142	6	4,23	136	95,77	NA	NA	NA	-	-	-	-	0,8633

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	total	-	SVd Arm	General disorders and administration site conditions	Pyrexia	195	31	15,90	164	84,10	NA	NA	NA	1,29	0,76	2,18	0,3383	NA
Patients with at least one AE	total	-	Vd Arm	General disorders and administration site conditions	Pyrexia	204	26	12,75	178	87,25	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	General disorders and administration site conditions	Fatigue	80	36	45,00	44	55,00	NA	3,98	NA	4,88	2,40	9,95	0,0000	0,0543
Patients with at least one AE	Gender	Female	Vd Arm	General disorders and administration site conditions	Fatigue	91	11	12,09	80	87,91	NA	NA	NA	-	-	-	-	0,0543
Patients with at least one AE	Gender	Male	SVd Arm	General disorders and administration site conditions	Fatigue	115	46	40,00	69	60,00	NA	8,87	NA	2,10	1,29	3,40	0,0023	0,0543
Patients with at least one AE	Gender	Male	Vd Arm	General disorders and administration site conditions	Fatigue	113	26	23,01	87	76,99	NA	NA	NA	-	-	-	-	0,0543
Patients with at least one AE	Age Group	<65	SVd Arm	General disorders and administration site conditions	Fatigue	86	34	39,53	52	60,47	NA	6,77	NA	2,54	1,33	4,88	0,0037	0,7183
Patients with at least one AE	Age Group	<65	Vd Arm	General disorders and administration site conditions	Fatigue	75	13	17,33	62	82,67	NA	NA	NA	-	-	-	-	0,7183
Patients with at least one AE	Age Group	>=65	SVd Arm	General disorders and administration site conditions	Fatigue	109	48	44,04	61	55,96	NA	3,98	NA	2,96	1,80	4,86	0,0000	0,7183
Patients with at least one AE	Age Group	>=65	Vd Arm	General disorders and administration site conditions	Fatigue	129	24	18,60	105	81,40	NA	NA	NA	-	-	-	-	0,7183
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Fatigue	173	71	41,04	102	58,96	NA	8,87	NA	2,74	1,79	4,19	0,0000	0,9545
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Fatigue	174	31	17,82	143	82,18	NA	NA	NA	-	-	-	-	0,9545
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Fatigue	12	4	33,33	8	66,67	NA	1,41	NA	2,60	0,44	15,23	0,2760	0,9545
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Fatigue	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,9545
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Fatigue	163	73	44,79	90	55,21	NA	5,59	NA	2,86	1,89	4,32	0,0000	0,8831
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Fatigue	173	33	19,08	140	80,92	NA	NA	NA	-	-	-	-	0,8831

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Fatigue	32	9	28,12	23	71,88	NA	NA	NA	3,17	0,83	12,07	0,0757	0,8831
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Fatigue	31	4	12,90	27	87,10	NA	NA	NA	-	-	-	-	0,8831
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	General disorders and administration site conditions	Fatigue	18	12	66,67	6	33,33	0,95	0,26	NA	4,35	1,19	15,87	0,0156	0,3102
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	General disorders and administration site conditions	Fatigue	17	5	29,41	12	70,59	NA	3,06	NA	-	-	-	-	0,3102
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	General disorders and administration site conditions	Fatigue	61	31	50,82	30	49,18	2,99	1,41	NA	1,97	1,11	3,48	0,0180	0,3102
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	General disorders and administration site conditions	Fatigue	64	20	31,25	44	68,75	NA	7,66	NA	-	-	-	-	0,3102
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	General disorders and administration site conditions	Fatigue	47	17	36,17	30	63,83	NA	10,84	NA	2,65	1,09	6,41	0,0252	0,3102
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	General disorders and administration site conditions	Fatigue	53	7	13,21	46	86,79	NA	NA	NA	-	-	-	-	0,3102
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	General disorders and administration site conditions	Fatigue	69	22	31,88	47	68,12	NA	NA	NA	5,32	2,01	14,09	0,0002	0,3102
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	General disorders and administration site conditions	Fatigue	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,3102
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	General disorders and administration site conditions	Fatigue	117	51	43,59	66	56,41	NA	6,47	NA	2,15	1,37	3,39	0,0007	0,0893
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	General disorders and administration site conditions	Fatigue	136	30	22,06	106	77,94	NA	NA	NA	-	-	-	-	0,0893
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	General disorders and administration site conditions	Fatigue	78	31	39,74	47	60,26	NA	5,39	NA	4,88	2,13	11,14	0,0000	0,0893
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	General disorders and administration site conditions	Fatigue	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,0893
Patients with at least one AE	Race	Races other than White	SVd Arm	General disorders and administration site conditions	Fatigue	34	15	44,12	19	55,88	NA	1,74	NA	3,69	1,37	9,94	0,0065	0,5319
Patients with at least one AE	Race	Races other than White	Vd Arm	General disorders and administration site conditions	Fatigue	42	7	16,67	35	83,33	NA	NA	NA	-	-	-	-	0,5319

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	SVd Arm	General disorders and administration site conditions	Fatigue	161	67	41,61	94	58,39	NA	8,87	NA	2,61	1,69	4,03	0,0000	0,5319
Patients with at least one AE	Race	White	Vd Arm	General disorders and administration site conditions	Fatigue	162	30	18,52	132	81,48	NA	NA	NA	-	-	-	-	0,5319
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Fatigue	6	1	16,67	5	83,33	NA	NA	NA	0,71	0,04	11,79	0,8084	0,3406
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Fatigue	5	2	40,00	3	60,00	NA	3,75	NA	-	-	-	-	0,3406
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Fatigue	171	73	42,69	98	57,31	NA	6,70	NA	2,82	1,87	4,24	0,0000	0,3406
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Fatigue	185	34	18,38	151	81,62	NA	NA	NA	-	-	-	-	0,3406
Patients with at least one AE	Prior PI therapies	N	SVd Arm	General disorders and administration site conditions	Fatigue	48	16	33,33	32	66,67	NA	NA	NA	1,72	0,79	3,74	0,1701	0,1629
Patients with at least one AE	Prior PI therapies	N	Vd Arm	General disorders and administration site conditions	Fatigue	47	11	23,40	36	76,60	NA	NA	NA	-	-	-	-	0,1629
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	General disorders and administration site conditions	Fatigue	147	66	44,90	81	55,10	NA	5,39	NA	3,26	2,07	5,14	0,0000	0,1629
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	General disorders and administration site conditions	Fatigue	157	26	16,56	131	83,44	NA	NA	NA	-	-	-	-	0,1629
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	General disorders and administration site conditions	Fatigue	98	37	37,76	61	62,24	NA	10,84	NA	2,31	1,33	4,02	0,0023	0,3536
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	General disorders and administration site conditions	Fatigue	104	19	18,27	85	81,73	NA	NA	NA	-	-	-	-	0,3536
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	General disorders and administration site conditions	Fatigue	97	45	46,39	52	53,61	NA	2,99	NA	3,35	1,93	5,80	0,0000	0,3536
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	General disorders and administration site conditions	Fatigue	100	18	18,00	82	82,00	NA	NA	NA	-	-	-	-	0,3536
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	General disorders and administration site conditions	Fatigue	98	37	37,76	61	62,24	NA	8,87	NA	2,83	1,61	5,00	0,0002	0,7342

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	General disorders and administration site conditions	Fatigue	111	18	16,22	93	83,78	NA	NA	NA	-	-	-	-	0,7342
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	General disorders and administration site conditions	Fatigue	97	45	46,39	52	53,61	10,84	3,98	NA	2,47	1,44	4,25	0,0007	0,7342
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	General disorders and administration site conditions	Fatigue	93	19	20,43	74	79,57	NA	NA	NA	-	-	-	-	0,7342
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	General disorders and administration site conditions	Fatigue	61	23	37,70	38	62,30	NA	6,70	NA	2,58	1,24	5,36	0,0087	0,7967
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	General disorders and administration site conditions	Fatigue	62	11	17,74	51	82,26	NA	NA	NA	-	-	-	-	0,7967
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	General disorders and administration site conditions	Fatigue	134	59	44,03	75	55,97	NA	5,39	NA	2,89	1,82	4,59	0,0000	0,7967
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	General disorders and administration site conditions	Fatigue	142	26	18,31	116	81,69	NA	NA	NA	-	-	-	-	0,7967
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	General disorders and administration site conditions	Fatigue	195	26	13,33	169	86,67	NA	NA	NA	14,82	3,48	63,03	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	General disorders and administration site conditions	Fatigue	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	General disorders and administration site conditions	Fatigue	80	12	15,00	68	85,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	General disorders and administration site conditions	Fatigue	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	General disorders and administration site conditions	Fatigue	115	14	12,17	101	87,83	NA	NA	NA	6,37	1,44	28,12	0,0051	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	General disorders and administration site conditions	Fatigue	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	General disorders and administration site conditions	Fatigue	86	7	8,14	79	91,86	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	General disorders and administration site conditions	Fatigue	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	General disorders and administration site conditions	Fatigue	109	19	17,43	90	82,57	NA	NA	NA	12,25	2,84	52,87	0,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	General disorders and administration site conditions	Fatigue	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Fatigue	173	24	13,87	149	86,13	NA	NA	NA	24,20	3,27	179,24	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Fatigue	174	1	0,57	173	99,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Fatigue	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Fatigue	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Fatigue	163	22	13,50	141	86,50	NA	NA	NA	11,75	2,76	50,09	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Fatigue	173	2	1,16	171	98,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Fatigue	32	4	12,50	28	87,50	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Fatigue	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	General disorders and administration site conditions	Fatigue	18	3	16,67	15	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	General disorders and administration site conditions	Fatigue	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	General disorders and administration site conditions	Fatigue	61	10	16,39	51	83,61	NA	NA	NA	4,96	1,08	22,73	0,0222	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	General disorders and administration site conditions	Fatigue	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	General disorders and administration site conditions	Fatigue	47	8	17,02	39	82,98	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	General disorders and administration site conditions	Fatigue	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	General disorders and administration site conditions	Fatigue	69	5	7,25	64	92,75	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	General disorders and administration site conditions	Fatigue	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	General disorders and administration site conditions	Fatigue	117	17	14,53	100	85,47	NA	NA	NA	19,66	2,59	149,10	0,0001	0,5514
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	General disorders and administration site conditions	Fatigue	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,5514
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	General disorders and administration site conditions	Fatigue	78	9	11,54	69	88,46	NA	NA	NA	8,16	1,03	64,48	0,0177	0,5514
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	General disorders and administration site conditions	Fatigue	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,5514
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	General disorders and administration site conditions	Fatigue	34	4	11,76	30	88,24	NA	NA	NA	3,78	0,39	36,55	0,2234	0,2420
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	General disorders and administration site conditions	Fatigue	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,2420
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	General disorders and administration site conditions	Fatigue	161	22	13,66	139	86,34	NA	NA	NA	23,17	3,08	174,41	0,0000	0,2420
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	General disorders and administration site conditions	Fatigue	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	0,2420
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Fatigue	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Fatigue	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Fatigue	171	24	14,04	147	85,96	NA	NA	NA	13,67	3,20	58,41	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Fatigue	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	General disorders and administration site conditions	Fatigue	48	7	14,58	41	85,42	NA	NA	NA	9,99	1,18	84,79	0,0115	0,6582
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	General disorders and administration site conditions	Fatigue	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,6582

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	General disorders and administration site conditions	Fatigue	147	19	12,93	128	87,07	NA	NA	NA	19,38	2,59	144,83	0,0000	0,6582
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	General disorders and administration site conditions	Fatigue	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,6582
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	General disorders and administration site conditions	Fatigue	98	14	14,29	84	85,71	NA	NA	NA	14,48	1,90	110,17	0,0006	0,9748
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	General disorders and administration site conditions	Fatigue	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	0,9748
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	General disorders and administration site conditions	Fatigue	97	12	12,37	85	87,63	NA	NA	NA	15,17	1,93	119,56	0,0008	0,9748
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	General disorders and administration site conditions	Fatigue	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,9748
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	General disorders and administration site conditions	Fatigue	98	14	14,29	84	85,71	NA	NA	NA	18,15	2,37	138,87	0,0001	0,7073
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	General disorders and administration site conditions	Fatigue	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	0,7073
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	General disorders and administration site conditions	Fatigue	97	12	12,37	85	87,63	NA	NA	NA	10,44	1,35	80,81	0,0054	0,7073
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	General disorders and administration site conditions	Fatigue	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,7073
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	General disorders and administration site conditions	Fatigue	61	10	16,39	51	83,61	NA	NA	NA	13,39	1,66	108,08	0,0021	0,8838
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	General disorders and administration site conditions	Fatigue	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,8838
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	General disorders and administration site conditions	Fatigue	134	16	11,94	118	88,06	NA	NA	NA	16,63	2,20	125,50	0,0002	0,8838
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	General disorders and administration site conditions	Fatigue	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	0,8838
Patients with at least one AE	total	-	SVd Arm	General disorders and administration site conditions	-	195	139	71,28	56	28,72	1,87	1,28	3,48	1,84	1,41	2,38	0,0000	NA
Patients with at least one AE	total	-	Vd Arm	General disorders and administration site conditions	-	204	101	49,51	103	50,49	6,90	5,36	25,46	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Female	SVd Arm	Nervous system disorders	Headache	80	9	11,25	71	88,75	NA	NA	NA	2,10	0,72	6,17	0,1687	0,8590
Patients with at least one AE	Gender	Female	Vd Arm	Nervous system disorders	Headache	91	7	7,69	84	92,31	NA	30,23	NA	-	-	-	-	0,8590
Patients with at least one AE	Gender	Male	SVd Arm	Nervous system disorders	Headache	115	11	9,57	104	90,43	NA	NA	NA	1,84	0,67	5,05	0,2308	0,8590
Patients with at least one AE	Gender	Male	Vd Arm	Nervous system disorders	Headache	113	6	5,31	107	94,69	NA	NA	NA	-	-	-	-	0,8590
Patients with at least one AE	Age Group	<65	SVd Arm	Nervous system disorders	Headache	86	10	11,63	76	88,37	NA	NA	NA	1,29	0,48	3,46	0,6136	0,4173
Patients with at least one AE	Age Group	<65	Vd Arm	Nervous system disorders	Headache	75	7	9,33	68	90,67	NA	30,23	NA	-	-	-	-	0,4173
Patients with at least one AE	Age Group	>=65	SVd Arm	Nervous system disorders	Headache	109	10	9,17	99	90,83	NA	NA	NA	2,32	0,84	6,44	0,0964	0,4173
Patients with at least one AE	Age Group	>=65	Vd Arm	Nervous system disorders	Headache	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	0,4173
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Headache	173	20	11,56	153	88,44	NA	NA	NA	2,13	0,99	4,57	0,0483	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Headache	174	10	5,75	164	94,25	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	Headache	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	Headache	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Headache	163	19	11,66	144	88,34	NA	NA	NA	1,75	0,85	3,61	0,1272	0,6352
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Headache	173	12	6,94	161	93,06	NA	NA	NA	-	-	-	-	0,6352
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	Headache	32	1	3,12	31	96,88	NA	NA	NA	0,82	0,04	17,32	0,8964	0,6352
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	Headache	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,6352
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	Headache	18	3	16,67	15	83,33	NA	7,66	NA	0,88	0,19	4,11	0,8692	0,6451
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	Headache	17	4	23,53	13	76,47	NA	NA	NA	-	-	-	-	0,6451
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	Headache	61	10	16,39	51	83,61	NA	NA	NA	2,89	0,91	9,23	0,0606	0,6451
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	Headache	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,6451
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	Headache	47	4	8,51	43	91,49	NA	NA	NA	1,69	0,37	7,71	0,4966	0,6451
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	Headache	53	4	7,55	49	92,45	30,23	30,23	NA	-	-	-	-	0,6451
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	Headache	69	3	4,35	66	95,65	NA	NA	NA	3,10	0,32	29,87	0,3012	0,6451
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	Headache	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,6451

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	Headache	117	14	11,97	103	88,03	NA	NA	NA	1,24	0,58	2,68	0,5740	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	Headache	136	13	9,56	123	90,44	NA	30,23	NA	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	Headache	78	6	7,69	72	92,31	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	Headache	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	SVd Arm	Nervous system disorders	Headache	34	1	2,94	33	97,06	NA	NA	NA	1,03	0,09	11,48	0,9792	0,6721
Patients with at least one AE	Race	Races other than White	Vd Arm	Nervous system disorders	Headache	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,6721
Patients with at least one AE	Race	White	SVd Arm	Nervous system disorders	Headache	161	19	11,80	142	88,20	NA	NA	NA	1,78	0,84	3,77	0,1273	0,6721
Patients with at least one AE	Race	White	Vd Arm	Nervous system disorders	Headache	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	0,6721
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Headache	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Headache	5	1	20,00	4	80,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Headache	171	17	9,94	154	90,06	NA	NA	NA	1,68	0,80	3,54	0,1680	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Headache	185	12	6,49	173	93,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Nervous system disorders	Headache	48	4	8,33	44	91,67	NA	NA	NA	3,76	0,42	33,73	0,2031	0,4421
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Nervous system disorders	Headache	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,4421
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Nervous system disorders	Headache	147	16	10,88	131	89,12	NA	NA	NA	1,52	0,71	3,22	0,2749	0,4421
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Nervous system disorders	Headache	157	12	7,64	145	92,36	NA	NA	NA	-	-	-	-	0,4421
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	Headache	98	6	6,12	92	93,88	NA	NA	NA	1,27	0,39	4,18	0,6895	0,5582
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	Headache	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,5582
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	Headache	97	14	14,43	83	85,57	NA	NA	NA	1,98	0,83	4,74	0,1188	0,5582

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	Headache	100	8	8,00	92	92,00	NA	30,23	NA	-	-	-	-	0,5582
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	Headache	98	12	12,24	86	87,76	NA	NA	NA	2,12	0,83	5,42	0,1070	0,5090
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	Headache	111	7	6,31	104	93,69	NA	NA	NA	-	-	-	-	0,5090
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	Headache	97	8	8,25	89	91,75	NA	NA	NA	1,31	0,45	3,84	0,6160	0,5090
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	Headache	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,5090
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	Headache	61	7	11,48	54	88,52	NA	NA	NA	4,20	0,86	20,45	0,0544	0,2473
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	Headache	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,2473
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	Headache	134	13	9,70	121	90,30	NA	NA	NA	1,46	0,64	3,35	0,3682	0,2473
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	Headache	142	10	7,04	132	92,96	NA	NA	NA	-	-	-	-	0,2473
Patients with at least one AE	total	-	SVd Arm	Infections and infestations	Bronchitis	195	25	12,82	170	87,18	NA	NA	NA	1,18	0,66	2,12	0,5772	NA
Patients with at least one AE	total	-	Vd Arm	Infections and infestations	Bronchitis	204	21	10,29	183	89,71	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	80	5	6,25	75	93,75	NA	NA	NA	2,32	0,54	9,93	0,2454	0,4475
Patients with at least one AE	Gender	Female	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,4475
Patients with at least one AE	Gender	Male	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	115	9	7,83	106	92,17	NA	NA	NA	1,18	0,45	3,09	0,7394	0,4475
Patients with at least one AE	Gender	Male	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	113	8	7,08	105	92,92	NA	NA	NA	-	-	-	-	0,4475
Patients with at least one AE	Age Group	<65	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	86	5	5,81	81	94,19	NA	NA	NA	1,57	0,37	6,76	0,5388	0,9325
Patients with at least one AE	Age Group	<65	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,9325
Patients with at least one AE	Age Group	>=65	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	109	9	8,26	100	91,74	NA	NA	NA	1,46	0,56	3,81	0,4368	0,9325
Patients with at least one AE	Age Group	>=65	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	129	8	6,20	121	93,80	NA	NA	NA	-	-	-	-	0,9325
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	173	10	5,78	163	94,22	NA	NA	NA	0,95	0,40	2,25	0,9075	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	174	11	6,32	163	93,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	12	3	25,00	9	75,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	163	10	6,13	153	93,87	NA	NA	NA	1,10	0,46	2,66	0,8244	0,2195
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	0,2195
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	32	4	12,50	28	87,50	NA	NA	NA	4,93	0,53	45,52	0,1219	0,2195
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,2195
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,8689
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,8689
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	61	4	6,56	57	93,44	NA	NA	NA	1,61	0,36	7,25	0,5334	0,8689
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,8689
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	47	3	6,38	44	93,62	NA	NA	NA	1,05	0,21	5,32	0,9554	0,8689
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,8689
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	69	4	5,80	65	94,20	NA	NA	NA	0,95	0,25	3,61	0,9397	0,8689
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,8689
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	117	10	8,55	107	91,45	NA	NA	NA	1,96	0,71	5,43	0,1877	0,3063
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	136	6	4,41	130	95,59	NA	NA	NA	-	-	-	-	0,3063
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	78	4	5,13	74	94,87	NA	NA	NA	0,81	0,21	3,13	0,7601	0,3063
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,3063
Patients with at least one AE	Race	Races other than White	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	34	3	8,82	31	91,18	NA	NA	NA	0,68	0,13	3,66	0,6482	0,2691
Patients with at least one AE	Race	Races other than White	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,2691
Patients with at least one AE	Race	White	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	161	11	6,83	150	93,17	NA	NA	NA	2,05	0,75	5,61	0,1544	0,2691

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	162	6	3,70	156	96,30	NA	NA	NA	-	-	-	-	0,2691
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	6	2	33,33	4	66,67	NA	0,95	NA	2,27	0,19	26,54	0,5019	0,7277
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	5	1	20,00	4	80,00	NA	6,24	NA	-	-	-	-	0,7277
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	171	11	6,43	160	93,57	NA	NA	NA	1,43	0,59	3,47	0,4271	0,7277
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	185	9	4,86	176	95,14	NA	NA	NA	-	-	-	-	0,7277
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	48	1	2,08	47	97,92	NA	NA	NA	0,32	0,03	3,12	0,3041	0,1583
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,1583
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	147	13	8,84	134	91,16	NA	NA	NA	1,86	0,77	4,51	0,1607	0,1583
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	157	8	5,10	149	94,90	NA	NA	NA	-	-	-	-	0,1583
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	98	6	6,12	92	93,88	NA	NA	NA	1,34	0,41	4,43	0,6268	0,9028
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,9028
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	97	8	8,25	89	91,75	NA	NA	NA	1,48	0,51	4,29	0,4633	0,9028
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,9028
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	98	5	5,10	93	94,90	NA	NA	NA	0,68	0,23	2,04	0,4887	0,0475
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	111	9	8,11	102	91,89	NA	NA	NA	-	-	-	-	0,0475
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	97	9	9,28	88	90,72	NA	NA	NA	4,61	0,99	21,50	0,0331	0,0475
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,0475
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	61	2	3,28	59	96,72	NA	NA	NA	0,32	0,03	3,12	0,3041	0,1919

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,1919
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	134	12	8,96	122	91,04	NA	NA	NA	1,64	0,67	4,02	0,2751	0,1919
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	142	8	5,63	134	94,37	NA	NA	NA	-	-	-	-	0,1919
Patients with at least one AE	total	-	SVd Arm	Infections and infestations	Influenza	195	12	6,15	183	93,85	NA	NA	NA	1,38	0,53	3,62	0,5089	NA
Patients with at least one AE	total	-	Vd Arm	Infections and infestations	Influenza	204	7	3,43	197	96,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Vascular disorders	Hypertension	80	10	12,50	70	87,50	NA	NA	NA	1,30	0,51	3,34	0,5790	0,8911
Patients with at least one AE	Gender	Female	Vd Arm	Vascular disorders	Hypertension	91	10	10,99	81	89,01	NA	NA	NA	-	-	-	-	0,8911
Patients with at least one AE	Gender	Male	SVd Arm	Vascular disorders	Hypertension	115	7	6,09	108	93,91	NA	NA	NA	1,18	0,39	3,55	0,7703	0,8911
Patients with at least one AE	Gender	Male	Vd Arm	Vascular disorders	Hypertension	113	6	5,31	107	94,69	NA	NA	NA	-	-	-	-	0,8911
Patients with at least one AE	Age Group	<65	SVd Arm	Vascular disorders	Hypertension	86	8	9,30	78	90,70	NA	NA	NA	1,92	0,50	7,44	0,3363	0,3301
Patients with at least one AE	Age Group	<65	Vd Arm	Vascular disorders	Hypertension	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,3301
Patients with at least one AE	Age Group	>=65	SVd Arm	Vascular disorders	Hypertension	109	9	8,26	100	91,74	NA	NA	NA	0,87	0,37	2,04	0,7447	0,3301
Patients with at least one AE	Age Group	>=65	Vd Arm	Vascular disorders	Hypertension	129	13	10,08	116	89,92	NA	NA	NA	-	-	-	-	0,3301
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Vascular disorders	Hypertension	173	16	9,25	157	90,75	NA	NA	NA	1,16	0,56	2,40	0,6854	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Vascular disorders	Hypertension	174	14	8,05	160	91,95	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Vascular disorders	Hypertension	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Vascular disorders	Hypertension	16	2	12,50	14	87,50	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Vascular disorders	Hypertension	163	15	9,20	148	90,80	NA	NA	NA	1,12	0,54	2,34	0,7558	0,4996
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Vascular disorders	Hypertension	173	14	8,09	159	91,91	NA	NA	NA	-	-	-	-	0,4996
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Vascular disorders	Hypertension	32	2	6,25	30	93,75	NA	NA	NA	2,69	0,24	30,40	0,4062	0,4996
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Vascular disorders	Hypertension	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,4996
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Vascular disorders	Hypertension	18	3	16,67	15	83,33	NA	11,86	NA	2,56	0,23	29,12	0,4328	0,1899
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Vascular disorders	Hypertension	17	3	17,65	14	82,35	NA	10,78	NA	-	-	-	-	0,1899
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Vascular disorders	Hypertension	61	8	13,11	53	86,89	NA	NA	NA	2,30	0,69	7,66	0,1622	0,1899
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Vascular disorders	Hypertension	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,1899
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Vascular disorders	Hypertension	47	2	4,26	45	95,74	NA	NA	NA	0,26	0,05	1,37	0,0911	0,1899
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Vascular disorders	Hypertension	53	6	11,32	47	88,68	NA	NA	NA	-	-	-	-	0,1899
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Vascular disorders	Hypertension	69	4	5,80	65	94,20	NA	NA	NA	1,24	0,28	5,56	0,7777	0,1899
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Vascular disorders	Hypertension	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	0,1899

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Vascular disorders	Hypertension	117	12	10,26	105	89,74	NA	NA	NA	1,04	0,47	2,32	0,9187	0,5895
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Vascular disorders	Hypertension	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,5895
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Vascular disorders	Hypertension	78	5	6,41	73	93,59	NA	NA	NA	1,64	0,39	6,87	0,4958	0,5895
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Vascular disorders	Hypertension	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,5895
Patients with at least one AE	Race	Races other than White	SVd Arm	Vascular disorders	Hypertension	34	4	11,76	30	88,24	NA	NA	NA	1,40	0,30	6,63	0,6692	0,7446
Patients with at least one AE	Race	Races other than White	Vd Arm	Vascular disorders	Hypertension	42	4	9,52	38	90,48	NA	NA	NA	-	-	-	-	0,7446
Patients with at least one AE	Race	White	SVd Arm	Vascular disorders	Hypertension	161	13	8,07	148	91,93	NA	NA	NA	1,05	0,47	2,32	0,9070	0,7446
Patients with at least one AE	Race	White	Vd Arm	Vascular disorders	Hypertension	162	12	7,41	150	92,59	NA	NA	NA	-	-	-	-	0,7446
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Vascular disorders	Hypertension	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Vascular disorders	Hypertension	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Vascular disorders	Hypertension	171	14	8,19	157	91,81	NA	NA	NA	0,97	0,47	2,01	0,9396	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Vascular disorders	Hypertension	185	16	8,65	169	91,35	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Vascular disorders	Hypertension	48	4	8,33	44	91,67	NA	NA	NA	0,99	0,24	4,02	0,9916	0,8544
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Vascular disorders	Hypertension	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,8544
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Vascular disorders	Hypertension	147	13	8,84	134	91,16	NA	NA	NA	1,15	0,52	2,54	0,7227	0,8544
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Vascular disorders	Hypertension	157	12	7,64	145	92,36	NA	NA	NA	-	-	-	-	0,8544
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Vascular disorders	Hypertension	98	6	6,12	92	93,88	NA	NA	NA	0,80	0,27	2,32	0,6739	0,4181
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Vascular disorders	Hypertension	104	8	7,69	96	92,31	NA	NA	NA	-	-	-	-	0,4181
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Vascular disorders	Hypertension	97	11	11,34	86	88,66	NA	NA	NA	1,42	0,57	3,55	0,4483	0,4181
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Vascular disorders	Hypertension	100	8	8,00	92	92,00	NA	NA	NA	-	-	-	-	0,4181

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Vascular disorders	Hypertension	98	4	4,08	94	95,92	NA	NA	NA	0,42	0,13	1,32	0,1260	0,0236
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Vascular disorders	Hypertension	111	11	9,91	100	90,09	NA	NA	NA	-	-	-	-	0,0236
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Vascular disorders	Hypertension	97	13	13,40	84	86,60	NA	NA	NA	2,53	0,89	7,22	0,0735	0,0236
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Vascular disorders	Hypertension	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,0236
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Vascular disorders	Hypertension	61	6	9,84	55	90,16	NA	NA	NA	0,94	0,31	2,82	0,9115	0,6186
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Vascular disorders	Hypertension	62	7	11,29	55	88,71	NA	NA	NA	-	-	-	-	0,6186
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Vascular disorders	Hypertension	134	11	8,21	123	91,79	NA	NA	NA	1,35	0,55	3,30	0,5131	0,6186
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Vascular disorders	Hypertension	142	9	6,34	133	93,66	NA	NA	NA	-	-	-	-	0,6186
Patients with at least one AE	total	-	SVd Arm	Infections and infestations	Lower respiratory tract infection	195	14	7,18	181	92,82	NA	NA	NA	1,21	0,54	2,71	0,6421	NA
Patients with at least one AE	total	-	Vd Arm	Infections and infestations	Lower respiratory tract infection	204	11	5,39	193	94,61	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	80	6	7,50	74	92,50	NA	NA	NA	3,36	0,66	17,10	0,1231	0,6943
Patients with at least one AE	Gender	Female	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,6943
Patients with at least one AE	Gender	Male	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	115	9	7,83	106	92,17	NA	NA	NA	2,24	0,68	7,36	0,1713	0,6943
Patients with at least one AE	Gender	Male	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,6943
Patients with at least one AE	Age Group	<65	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	86	6	6,98	80	93,02	NA	NA	NA	7,00	0,77	63,66	0,0536	0,3871
Patients with at least one AE	Age Group	<65	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,3871
Patients with at least one AE	Age Group	>=65	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	109	9	8,26	100	91,74	NA	NA	NA	2,35	0,78	7,08	0,1164	0,3871
Patients with at least one AE	Age Group	>=65	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,3871
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	173	13	7,51	160	92,49	NA	NA	NA	2,46	0,87	6,97	0,0806	0,8882
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	174	5	2,87	169	97,13	NA	NA	NA	-	-	-	-	0,8882

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	12	2	16,67	10	83,33	NA	6,37	NA	3,00	0,23	39,34	0,3883	0,8882
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,8882
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	163	12	7,36	151	92,64	NA	NA	NA	4,11	1,15	14,69	0,0186	0,1692
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	0,1692
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	32	3	9,38	29	90,62	NA	NA	NA	0,94	0,17	5,03	0,9383	0,1692
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,1692
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,3821
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,3821
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	61	5	8,20	56	91,80	NA	NA	NA	6,64	0,75	58,80	0,0528	0,3821
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,3821
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	47	3	6,38	44	93,62	NA	NA	NA	2,82	0,29	27,51	0,3508	0,3821
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,3821
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	69	4	5,80	65	94,20	NA	NA	NA	1,10	0,26	4,58	0,8969	0,3821
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	70	4	5,71	66	94,29	NA	NA	NA	-	-	-	-	0,3821
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	117	10	8,55	107	91,45	NA	NA	NA	3,51	0,96	12,81	0,0433	0,4330
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	136	3	2,21	133	97,79	NA	NA	NA	-	-	-	-	0,4330
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	78	5	6,41	73	93,59	NA	NA	NA	1,60	0,37	6,95	0,5256	0,4330
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,4330
Patients with at least one AE	Race	Races other than White	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	34	2	5,88	32	94,12	NA	NA	NA	1,05	0,15	7,52	0,9643	0,3553
Patients with at least one AE	Race	Races other than White	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,3553
Patients with at least one AE	Race	White	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	161	13	8,07	148	91,93	NA	NA	NA	3,06	0,99	9,47	0,0419	0,3553
Patients with at least one AE	Race	White	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	162	4	2,47	158	97,53	NA	NA	NA	-	-	-	-	0,3553

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	171	11	6,43	160	93,57	NA	NA	NA	1,96	0,71	5,39	0,1871	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	185	6	3,24	179	96,76	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	48	3	6,25	45	93,75	NA	NA	NA	1,09	0,17	6,92	0,9275	0,2952
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	47	2	4,26	45	95,74	NA	29,01	NA	-	-	-	-	0,2952
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	147	12	8,16	135	91,84	NA	NA	NA	3,47	1,11	10,83	0,0225	0,2952
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	157	4	2,55	153	97,45	NA	NA	NA	-	-	-	-	0,2952
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	98	6	6,12	92	93,88	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	97	9	9,28	88	90,72	NA	NA	NA	1,45	0,51	4,14	0,4823	NA
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	98	9	9,18	89	90,82	NA	NA	NA	6,07	1,29	28,50	0,0098	0,1625
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,1625
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	97	6	6,19	91	93,81	NA	NA	NA	1,46	0,41	5,20	0,5613	0,1625
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	93	4	4,30	89	95,70	NA	29,01	NA	-	-	-	-	0,1625
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	61	3	4,92	58	95,08	NA	NA	NA	0,84	0,16	4,51	0,8394	0,1076
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	62	3	4,84	59	95,16	NA	29,01	NA	-	-	-	-	0,1076

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	134	12	8,96	122	91,04	NA	NA	NA	4,75	1,33	17,03	0,0085	0,1076
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	142	3	2,11	139	97,89	NA	NA	NA	-	-	-	-	0,1076
Patients with at least one AE	total	-	SVd Arm	Infections and infestations	Nasopharyngitis	195	23	11,79	172	88,21	NA	NA	NA	2,49	1,18	5,27	0,0136	NA
Patients with at least one AE	total	-	Vd Arm	Infections and infestations	Nasopharyngitis	204	11	5,39	193	94,61	NA	39,36	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	80	13	16,25	67	83,75	NA	NA	NA	2,41	0,90	6,45	0,0707	0,3841
Patients with at least one AE	Gender	Female	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	91	7	7,69	84	92,31	NA	NA	NA	-	-	-	-	0,3841
Patients with at least one AE	Gender	Male	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	115	5	4,35	110	95,65	NA	NA	NA	1,15	0,30	4,41	0,8366	0,3841
Patients with at least one AE	Gender	Male	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,3841
Patients with at least one AE	Age Group	<65	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	86	6	6,98	80	93,02	NA	NA	NA	5,34	0,62	46,14	0,0931	0,2779
Patients with at least one AE	Age Group	<65	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,2779
Patients with at least one AE	Age Group	>=65	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	109	12	11,01	97	88,99	NA	NA	NA	1,48	0,63	3,46	0,3638	0,2779
Patients with at least one AE	Age Group	>=65	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	129	10	7,75	119	92,25	NA	NA	NA	-	-	-	-	0,2779
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	173	16	9,25	157	90,75	NA	NA	NA	2,00	0,85	4,72	0,1073	0,4984
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	0,4984
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	12	2	16,67	10	83,33	NA	NA	NA	0,91	0,11	7,56	0,9282	0,4984
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,4984
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	163	15	9,20	148	90,80	NA	NA	NA	1,67	0,73	3,84	0,2237	0,9886
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	173	9	5,20	164	94,80	NA	NA	NA	-	-	-	-	0,9886
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	32	3	9,38	29	90,62	NA	NA	NA	1,64	0,26	10,27	0,5917	0,9886
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,9886
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	18	3	16,67	15	83,33	NA	NA	NA	2,21	0,23	21,31	0,4818	0,8326
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,8326
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	61	10	16,39	51	83,61	NA	NA	NA	2,21	0,74	6,61	0,1468	0,8326

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,8326
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	47	2	4,26	45	95,74	NA	NA	NA	1,76	0,15	20,11	0,6465	0,8326
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,8326
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	69	3	4,35	66	95,65	NA	NA	NA	0,89	0,17	4,57	0,8887	0,8326
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	0,8326
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	117	14	11,97	103	88,03	NA	NA	NA	2,01	0,84	4,81	0,1122	0,5273
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	136	8	5,88	128	94,12	NA	NA	NA	-	-	-	-	0,5273
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	78	4	5,13	74	94,87	NA	NA	NA	1,14	0,25	5,24	0,8690	0,5273
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,5273
Patients with at least one AE	Race	Races other than White	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	34	3	8,82	31	91,18	NA	NA	NA	2,09	0,34	12,72	0,4150	0,8184
Patients with at least one AE	Race	Races other than White	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,8184
Patients with at least one AE	Race	White	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	161	15	9,32	146	90,68	NA	NA	NA	1,65	0,71	3,83	0,2374	0,8184
Patients with at least one AE	Race	White	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	162	9	5,56	153	94,44	NA	NA	NA	-	-	-	-	0,8184
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	171	13	7,60	158	92,40	NA	NA	NA	1,40	0,60	3,26	0,4272	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	185	10	5,41	175	94,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	48	3	6,25	45	93,75	NA	NA	NA	0,84	0,15	4,55	0,8357	0,3544
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	47	3	6,38	44	93,62	NA	29,01	NA	-	-	-	-	0,3544

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	147	15	10,20	132	89,80	NA	NA	NA	2,05	0,87	4,85	0,0945	0,3544
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	157	8	5,10	149	94,90	NA	NA	NA	-	-	-	-	0,3544
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	98	7	7,14	91	92,86	NA	NA	NA	2,50	0,64	9,68	0,1707	0,5008
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,5008
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	97	11	11,34	86	88,66	NA	NA	NA	1,42	0,56	3,59	0,4552	0,5008
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	100	8	8,00	92	92,00	NA	NA	NA	-	-	-	-	0,5008
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	98	11	11,22	87	88,78	NA	NA	NA	4,30	1,19	15,55	0,0156	0,0353
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	0,0353
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	97	7	7,22	90	92,78	NA	NA	NA	0,74	0,26	2,05	0,5569	0,0353
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	93	8	8,60	85	91,40	NA	29,01	NA	-	-	-	-	0,0353
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	61	4	6,56	57	93,44	NA	NA	NA	0,84	0,15	4,55	0,8357	0,4093
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	62	3	4,84	59	95,16	NA	29,01	NA	-	-	-	-	0,4093
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	134	14	10,45	120	89,55	NA	NA	NA	1,86	0,78	4,46	0,1547	0,4093
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	142	8	5,63	134	94,37	NA	NA	NA	-	-	-	-	0,4093
Patients with at least one AE	total	-	SVd Arm	Infections and infestations	Pneumonia	195	33	16,92	162	83,08	NA	NA	NA	1,10	0,67	1,80	0,7080	NA
Patients with at least one AE	total	-	Vd Arm	Infections and infestations	Pneumonia	204	32	15,69	172	84,31	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	80	6	7,50	74	92,50	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Female	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Male	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	115	7	6,09	108	93,91	NA	NA	NA	2,33	0,60	9,05	0,2088	NA
Patients with at least one AE	Gender	Male	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	113	3	2,65	110	97,35	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	<65	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	86	6	6,98	80	93,02	NA	NA	NA	2,46	0,49	12,46	0,2611	0,3765
Patients with at least one AE	Age Group	<65	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,3765
Patients with at least one AE	Age Group	>=65	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	109	7	6,42	102	93,58	NA	NA	NA	8,16	1,00	66,80	0,0201	0,3765
Patients with at least one AE	Age Group	>=65	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	0,3765
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	173	9	5,20	164	94,80	NA	NA	NA	3,36	0,90	12,55	0,0565	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	12	3	25,00	9	75,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	163	9	5,52	154	94,48	NA	NA	NA	3,25	0,88	12,05	0,0623	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	32	4	12,50	28	87,50	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,4237
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,4237
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	61	6	9,84	55	90,16	NA	NA	NA	7,81	0,91	66,69	0,0284	0,4237
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,4237
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,4237
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,4237
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	69	5	7,25	64	92,75	NA	NA	NA	2,59	0,50	13,38	0,2375	0,4237
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,4237
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	117	7	5,98	110	94,02	NA	NA	NA	8,57	1,04	70,60	0,0173	0,3595
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,3595
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	78	6	7,69	72	92,31	NA	NA	NA	2,48	0,50	12,37	0,2511	0,3595

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,3595
Patients with at least one AE	Race	Races other than White	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	34	4	11,76	30	88,24	NA	NA	NA	2,47	0,43	14,19	0,2955	0,3296
Patients with at least one AE	Race	Races other than White	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,3296
Patients with at least one AE	Race	White	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	161	9	5,59	152	94,41	NA	NA	NA	9,52	1,20	75,52	0,0093	0,3296
Patients with at least one AE	Race	White	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	0,3296
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	171	11	6,43	160	93,57	NA	NA	NA	4,02	1,12	14,45	0,0213	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	185	3	1,62	182	98,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	48	3	6,25	45	93,75	NA	NA	NA	3,09	0,32	29,76	0,3047	0,6746
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,6746
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	147	10	6,80	137	93,20	NA	NA	NA	5,54	1,21	25,33	0,0131	0,6746
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,6746
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	98	6	6,12	92	93,88	NA	NA	NA	3,19	0,64	15,81	0,1341	0,5063
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	0,5063
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	97	7	7,22	90	92,78	NA	NA	NA	7,80	0,96	63,63	0,0233	0,5063
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,5063
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	98	7	7,14	91	92,86	NA	NA	NA	4,26	0,88	20,57	0,0493	0,7973
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,7973

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	97	6	6,19	91	93,81	NA	NA	NA	6,03	0,72	50,25	0,0590	0,7973
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,7973
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	61	3	4,92	58	95,08	NA	NA	NA	3,09	0,32	29,76	0,3047	0,6847
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,6847
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	134	10	7,46	124	92,54	NA	NA	NA	5,43	1,19	24,88	0,0145	0,6847
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,6847
Patients with at least one AE	total	-	SVd Arm	Infections and infestations	Respiratory tract infection	195	16	8,21	179	91,79	NA	44,16	NA	1,96	0,83	4,63	0,1187	NA
Patients with at least one AE	total	-	Vd Arm	Infections and infestations	Respiratory tract infection	204	8	3,92	196	96,08	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	80	8	10,00	72	90,00	NA	NA	NA	2,90	0,75	11,13	0,1058	0,6119
Patients with at least one AE	Gender	Female	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,6119
Patients with at least one AE	Gender	Male	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	115	8	6,96	107	93,04	NA	NA	NA	1,81	0,53	6,16	0,3367	0,6119
Patients with at least one AE	Gender	Male	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,6119
Patients with at least one AE	Age Group	<65	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	86	9	10,47	77	89,53	NA	NA	NA	3,49	0,74	16,53	0,0951	0,4276
Patients with at least one AE	Age Group	<65	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,4276
Patients with at least one AE	Age Group	>=65	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	109	7	6,42	102	93,58	NA	NA	NA	1,59	0,50	5,09	0,4309	0,4276
Patients with at least one AE	Age Group	>=65	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,4276
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	173	13	7,51	160	92,49	NA	NA	NA	1,69	0,67	4,29	0,2619	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	174	7	4,02	167	95,98	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	163	14	8,59	149	91,41	NA	NA	NA	1,92	0,77	4,79	0,1559	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	173	7	4,05	166	95,95	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	18	4	22,22	14	77,78	-	-	-	-	-	-	-	0,3836
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,3836
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	61	9	14,75	52	85,25	NA	NA	NA	2,37	0,72	7,82	0,1459	0,3836
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,3836
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,3836
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	0,3836
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	69	3	4,35	66	95,65	NA	NA	NA	0,96	0,18	4,98	0,9589	0,3836
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	0,3836
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	117	10	8,55	107	91,45	NA	NA	NA	2,59	0,81	8,30	0,0957	0,6236
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	136	4	2,94	132	97,06	NA	NA	NA	-	-	-	-	0,6236
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	78	6	7,69	72	92,31	NA	NA	NA	1,64	0,40	6,74	0,4888	0,6236
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,6236
Patients with at least one AE	Race	Races other than White	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	34	3	8,82	31	91,18	NA	NA	NA	4,80	0,48	48,11	0,1452	0,5535
Patients with at least one AE	Race	Races other than White	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,5535
Patients with at least one AE	Race	White	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	161	13	8,07	148	91,93	NA	NA	NA	2,23	0,79	6,34	0,1209	0,5535
Patients with at least one AE	Race	White	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	162	5	3,09	157	96,91	NA	NA	NA	-	-	-	-	0,5535
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	171	15	8,77	156	91,23	NA	NA	NA	2,18	0,88	5,40	0,0856	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	185	7	3,78	178	96,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	48	2	4,17	46	95,83	NA	NA	NA	0,64	0,08	5,13	0,6704	0,1977
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	47	2	4,26	45	95,74	NA	29,01	NA	-	-	-	-	0,1977
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	147	14	9,52	133	90,48	NA	NA	NA	2,94	1,05	8,18	0,0308	0,1977
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	157	5	3,18	152	96,82	NA	NA	NA	-	-	-	-	0,1977
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	98	6	6,12	92	93,88	NA	NA	NA	1,23	0,37	4,04	0,7371	0,1690
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,1690
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	97	10	10,31	87	89,69	NA	NA	NA	4,78	1,04	22,05	0,0271	0,1690
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,1690
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	98	10	10,20	88	89,80	NA	NA	NA	3,20	1,00	10,29	0,0390	0,4224
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,4224
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	97	6	6,19	91	93,81	NA	NA	NA	1,52	0,37	6,18	0,5570	0,4224
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	93	3	3,23	90	96,77	NA	29,01	NA	-	-	-	-	0,4224
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	61	2	3,28	59	96,72	NA	NA	NA	0,64	0,08	5,13	0,6704	0,1969
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	62	2	3,23	60	96,77	NA	29,01	NA	-	-	-	-	0,1969
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	134	14	10,45	120	89,55	NA	NA	NA	2,95	1,06	8,22	0,0307	0,1969
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	142	5	3,52	137	96,48	NA	NA	NA	-	-	-	-	0,1969

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	195	10	5,13	185	94,87	NA	NA	NA	3,45	0,94	12,58	0,0464	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	204	3	1,47	201	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	80	5	6,25	75	93,75	NA	NA	NA	4,83	0,56	42,05	0,1163	0,6485
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,6485
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	115	5	4,35	110	95,65	NA	NA	NA	2,56	0,48	13,63	0,2555	0,6485
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,6485
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	86	6	6,98	80	93,02	NA	NA	NA	2,43	0,48	12,42	0,2715	0,6164
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,6164
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	109	4	3,67	105	96,33	NA	NA	NA	4,90	0,54	44,32	0,1183	0,6164
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	0,6164
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	173	8	4,62	165	95,38	NA	NA	NA	2,53	0,67	9,55	0,1566	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	163	9	5,52	154	94,48	NA	NA	NA	2,99	0,81	11,07	0,0844	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,9848
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,9848
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	61	5	8,20	56	91,80	NA	NA	NA	2,42	0,47	12,51	0,2774	0,9848
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	0,9848
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,9848
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	0,9848
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	69	2	2,90	67	97,10	NA	NA	NA	2,35	0,21	26,41	0,4765	0,9848
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,9848
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	117	7	5,98	110	94,02	NA	NA	NA	3,56	0,74	17,19	0,0915	0,8084
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	0,8084
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	78	3	3,85	75	96,15	NA	NA	NA	2,53	0,26	24,75	0,4102	0,8084
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,8084
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	34	2	5,88	32	94,12	NA	NA	NA	3,20	0,27	38,00	0,3353	0,6352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,6352

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	161	8	4,97	153	95,03	NA	NA	NA	7,00	0,87	56,00	0,0327	0,6352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	0,6352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	171	10	5,85	161	94,15	NA	NA	NA	3,58	0,98	13,13	0,0400	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	185	3	1,62	182	98,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	48	1	2,08	47	97,92	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	147	9	6,12	138	93,88	NA	NA	NA	3,16	0,85	11,73	0,0698	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	157	3	1,91	154	98,09	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	98	4	4,08	94	95,92	NA	NA	NA	1,42	0,31	6,40	0,6483	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	97	6	6,19	91	93,81	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	98	7	7,14	91	92,86	NA	NA	NA	4,50	0,92	21,88	0,0421	0,6838

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,6838
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	97	3	3,09	94	96,91	NA	NA	NA	2,53	0,26	24,44	0,4060	0,6838
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,6838
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	134	9	6,72	125	93,28	NA	NA	NA	3,18	0,85	11,87	0,0693	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	142	3	2,11	139	97,89	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Infections and infestations	Upper respiratory tract infection	195	30	15,38	165	84,62	NA	NA	NA	1,21	0,70	2,09	0,4863	NA
Patients with at least one AE	total	-	Vd Arm	Infections and infestations	Upper respiratory tract infection	204	25	12,25	179	87,75	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Vascular disorders	Hypotension	80	6	7,50	74	92,50	NA	NA	NA	1,25	0,39	3,95	0,7061	0,6232
Patients with at least one AE	Gender	Female	Vd Arm	Vascular disorders	Hypotension	91	6	6,59	85	93,41	NA	NA	NA	-	-	-	-	0,6232
Patients with at least one AE	Gender	Male	SVd Arm	Vascular disorders	Hypotension	115	5	4,35	110	95,65	NA	NA	NA	0,82	0,24	2,75	0,7486	0,6232
Patients with at least one AE	Gender	Male	Vd Arm	Vascular disorders	Hypotension	113	6	5,31	107	94,69	NA	NA	NA	-	-	-	-	0,6232
Patients with at least one AE	Age Group	<65	SVd Arm	Vascular disorders	Hypotension	86	6	6,98	80	93,02	NA	NA	NA	1,30	0,36	4,73	0,6915	0,6238
Patients with at least one AE	Age Group	<65	Vd Arm	Vascular disorders	Hypotension	75	4	5,33	71	94,67	NA	NA	NA	-	-	-	-	0,6238
Patients with at least one AE	Age Group	>=65	SVd Arm	Vascular disorders	Hypotension	109	5	4,59	104	95,41	NA	NA	NA	0,85	0,27	2,61	0,7699	0,6238
Patients with at least one AE	Age Group	>=65	Vd Arm	Vascular disorders	Hypotension	129	8	6,20	121	93,80	NA	NA	NA	-	-	-	-	0,6238
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Vascular disorders	Hypotension	173	11	6,36	162	93,64	NA	NA	NA	1,35	0,55	3,29	0,5138	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Vascular disorders	Hypotension	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Vascular disorders	Hypotension	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Vascular disorders	Hypotension	16	2	12,50	14	87,50	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Vascular disorders	Hypotension	163	8	4,91	155	95,09	NA	NA	NA	0,97	0,37	2,53	0,9572	0,5825
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Vascular disorders	Hypotension	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	0,5825
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Vascular disorders	Hypotension	32	3	9,38	29	90,62	NA	NA	NA	1,73	0,28	10,54	0,5483	0,5825

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Vascular disorders	Hypotension	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,5825
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Vascular disorders	Hypotension	18	4	22,22	14	77,78	-	-	-	-	-	-	-	0,6726
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Vascular disorders	Hypotension	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,6726
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Vascular disorders	Hypotension	61	2	3,28	59	96,72	NA	NA	NA	0,41	0,08	2,16	0,2778	0,6726
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Vascular disorders	Hypotension	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,6726
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Vascular disorders	Hypotension	47	1	2,13	46	97,87	NA	NA	NA	0,78	0,07	8,94	0,8440	0,6726
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Vascular disorders	Hypotension	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,6726
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Vascular disorders	Hypotension	69	4	5,80	65	94,20	NA	NA	NA	1,10	0,27	4,48	0,8947	0,6726
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Vascular disorders	Hypotension	70	4	5,71	66	94,29	NA	NA	NA	-	-	-	-	0,6726
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Vascular disorders	Hypotension	117	7	5,98	110	94,02	NA	NA	NA	1,23	0,42	3,57	0,7016	0,7391
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Vascular disorders	Hypotension	136	8	5,88	128	94,12	NA	NA	NA	-	-	-	-	0,7391
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Vascular disorders	Hypotension	78	4	5,13	74	94,87	NA	NA	NA	0,91	0,22	3,71	0,8983	0,7391
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Vascular disorders	Hypotension	68	4	5,88	64	94,12	NA	NA	NA	-	-	-	-	0,7391
Patients with at least one AE	Race	Races other than White	SVd Arm	Vascular disorders	Hypotension	34	3	8,82	31	91,18	NA	NA	NA	4,22	0,42	41,99	0,1845	0,1888
Patients with at least one AE	Race	Races other than White	Vd Arm	Vascular disorders	Hypotension	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,1888
Patients with at least one AE	Race	White	SVd Arm	Vascular disorders	Hypotension	161	8	4,97	153	95,03	NA	NA	NA	0,80	0,32	2,03	0,6416	0,1888
Patients with at least one AE	Race	White	Vd Arm	Vascular disorders	Hypotension	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	0,1888
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Vascular disorders	Hypotension	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Vascular disorders	Hypotension	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Vascular disorders	Hypotension	171	11	6,43	160	93,57	NA	NA	NA	1,12	0,49	2,56	0,7970	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Vascular disorders	Hypotension	185	12	6,49	173	93,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Vascular disorders	Hypotension	48	2	4,17	46	95,83	NA	NA	NA	2,46	0,21	28,15	0,4558	0,4632
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Vascular disorders	Hypotension	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,4632
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Vascular disorders	Hypotension	147	9	6,12	138	93,88	NA	NA	NA	0,93	0,38	2,26	0,8753	0,4632

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Vascular disorders	Hypotension	157	11	7,01	146	92,99	NA	NA	NA	-	-	-	-	0,4632
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Vascular disorders	Hypotension	98	3	3,06	95	96,94	NA	NA	NA	0,50	0,13	1,95	0,3105	0,1543
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Vascular disorders	Hypotension	104	7	6,73	97	93,27	NA	NA	NA	-	-	-	-	0,1543
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Vascular disorders	Hypotension	97	8	8,25	89	91,75	NA	NA	NA	1,81	0,59	5,58	0,2952	0,1543
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Vascular disorders	Hypotension	100	5	5,00	95	95,00	NA	NA	NA	-	-	-	-	0,1543
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Vascular disorders	Hypotension	98	7	7,14	91	92,86	NA	NA	NA	1,09	0,39	3,08	0,8681	0,9008
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Vascular disorders	Hypotension	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,9008
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Vascular disorders	Hypotension	97	4	4,12	93	95,88	NA	NA	NA	0,98	0,24	3,92	0,9747	0,9008
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Vascular disorders	Hypotension	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,9008
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Vascular disorders	Hypotension	61	2	3,28	59	96,72	NA	NA	NA	2,46	0,21	28,15	0,4558	0,4751
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Vascular disorders	Hypotension	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,4751
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Vascular disorders	Hypotension	134	9	6,72	125	93,28	NA	NA	NA	0,96	0,39	2,33	0,9195	0,4751
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Vascular disorders	Hypotension	142	11	7,75	131	92,25	NA	NA	NA	-	-	-	-	0,4751
Patients with at least one AE	total	-	SVd Arm	Infections and infestations	Urinary tract infection	195	14	7,18	181	92,82	NA	42,74	NA	1,48	0,63	3,49	0,3650	NA
Patients with at least one AE	total	-	Vd Arm	Infections and infestations	Urinary tract infection	204	9	4,41	195	95,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Infections and infestations	Influenza	80	5	6,25	75	93,75	NA	NA	NA	2,84	0,54	14,86	0,1980	0,3197
Patients with at least one AE	Gender	Female	Vd Arm	Infections and infestations	Influenza	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,3197
Patients with at least one AE	Gender	Male	SVd Arm	Infections and infestations	Influenza	115	7	6,09	108	93,91	NA	NA	NA	1,00	0,30	3,34	0,9957	0,3197
Patients with at least one AE	Gender	Male	Vd Arm	Infections and infestations	Influenza	113	5	4,42	108	95,58	NA	NA	NA	-	-	-	-	0,3197
Patients with at least one AE	Age Group	<65	SVd Arm	Infections and infestations	Influenza	86	5	5,81	81	94,19	NA	NA	NA	3,97	0,44	36,13	0,1876	0,3357

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	<65	Vd Arm	Infections and infestations	Influenza	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,3357
Patients with at least one AE	Age Group	>=65	SVd Arm	Infections and infestations	Influenza	109	7	6,42	102	93,58	NA	NA	NA	1,17	0,37	3,69	0,7901	0,3357
Patients with at least one AE	Age Group	>=65	Vd Arm	Infections and infestations	Influenza	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	0,3357
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Influenza	173	11	6,36	162	93,64	NA	NA	NA	1,17	0,44	3,15	0,7535	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Influenza	174	7	4,02	167	95,98	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Influenza	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Influenza	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Influenza	163	10	6,13	153	93,87	NA	NA	NA	1,25	0,47	3,36	0,6520	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Influenza	173	7	4,05	166	95,95	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Influenza	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Influenza	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Influenza	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,1965
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Influenza	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,1965
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Influenza	61	6	9,84	55	90,16	NA	NA	NA	2,03	0,47	8,71	0,3320	0,1965
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Influenza	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,1965
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Influenza	47	3	6,38	44	93,62	-	-	-	-	-	-	-	0,1965
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Influenza	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,1965
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Influenza	69	2	2,90	67	97,10	NA	NA	NA	0,30	0,02	3,72	0,3248	0,1965
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Influenza	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,1965
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Influenza	117	9	7,69	108	92,31	NA	NA	NA	2,27	0,69	7,53	0,1686	0,1810
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Influenza	136	4	2,94	132	97,06	NA	NA	NA	-	-	-	-	0,1810
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Influenza	78	3	3,85	75	96,15	NA	NA	NA	0,50	0,08	3,24	0,4594	0,1810

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Influenza	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,1810
Patients with at least one AE	Race	Races other than White	SVd Arm	Infections and infestations	Influenza	34	0	0,00	34	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Infections and infestations	Influenza	42	2	4,76	40	95,24	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Infections and infestations	Influenza	161	12	7,45	149	92,55	NA	NA	NA	2,12	0,72	6,26	0,1633	NA
Patients with at least one AE	Race	White	Vd Arm	Infections and infestations	Influenza	162	5	3,09	157	96,91	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Influenza	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Influenza	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Influenza	171	10	5,85	161	94,15	NA	NA	NA	1,34	0,47	3,85	0,5798	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Influenza	185	6	3,24	179	96,76	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Infections and infestations	Influenza	48	5	10,42	43	89,58	NA	NA	NA	1,03	0,22	4,74	0,9743	0,6293
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Infections and infestations	Influenza	47	3	6,38	44	93,62	NA	19,25	NA	-	-	-	-	0,6293
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Infections and infestations	Influenza	147	7	4,76	140	95,24	NA	NA	NA	1,67	0,48	5,77	0,4156	0,6293
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Infections and infestations	Influenza	157	4	2,55	153	97,45	NA	NA	NA	-	-	-	-	0,6293
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Influenza	98	6	6,12	92	93,88	NA	NA	NA	0,94	0,27	3,25	0,9237	0,3519
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Influenza	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,3519
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Influenza	97	6	6,19	91	93,81	NA	NA	NA	2,50	0,48	12,88	0,2589	0,3519
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Influenza	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,3519
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Influenza	98	8	8,16	90	91,84	NA	NA	NA	7,39	0,88	61,96	0,0336	0,0379
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Influenza	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	0,0379

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Influenza	97	4	4,12	93	95,88	NA	NA	NA	0,53	0,15	1,92	0,3269	0,0379
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Influenza	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,0379
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Influenza	61	6	9,84	55	90,16	NA	NA	NA	1,61	0,36	7,28	0,5309	0,8956
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Influenza	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,8956
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Influenza	134	6	4,48	128	95,52	NA	NA	NA	1,41	0,39	5,09	0,5951	0,8956
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Influenza	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,8956
Patients with at least one AE	total	-	SVd Arm	Infections and infestations	-	195	138	70,77	57	29,23	3,65	2,99	4,96	1,24	0,97	1,59	0,0899	NA
Patients with at least one AE	total	-	Vd Arm	Infections and infestations	-	204	120	58,82	84	41,18	4,17	3,06	6,64	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Psychiatric disorders	Insomnia	80	11	13,75	69	86,25	NA	NA	NA	0,94	0,41	2,13	0,8802	0,8309
Patients with at least one AE	Gender	Female	Vd Arm	Psychiatric disorders	Insomnia	91	13	14,29	78	85,71	NA	NA	NA	-	-	-	-	0,8309
Patients with at least one AE	Gender	Male	SVd Arm	Psychiatric disorders	Insomnia	115	20	17,39	95	82,61	NA	NA	NA	1,05	0,56	1,98	0,8775	0,8309
Patients with at least one AE	Gender	Male	Vd Arm	Psychiatric disorders	Insomnia	113	19	16,81	94	83,19	NA	NA	NA	-	-	-	-	0,8309
Patients with at least one AE	Age Group	<65	SVd Arm	Psychiatric disorders	Insomnia	86	11	12,79	75	87,21	NA	NA	NA	0,47	0,22	1,01	0,0488	0,0233
Patients with at least one AE	Age Group	<65	Vd Arm	Psychiatric disorders	Insomnia	75	17	22,67	58	77,33	NA	NA	NA	-	-	-	-	0,0233
Patients with at least one AE	Age Group	>=65	SVd Arm	Psychiatric disorders	Insomnia	109	20	18,35	89	81,65	NA	NA	NA	1,54	0,78	3,02	0,2110	0,0233
Patients with at least one AE	Age Group	>=65	Vd Arm	Psychiatric disorders	Insomnia	129	15	11,63	114	88,37	NA	NA	NA	-	-	-	-	0,0233
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Psychiatric disorders	Insomnia	173	31	17,92	142	82,08	NA	NA	NA	1,14	0,68	1,92	0,6195	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Psychiatric disorders	Insomnia	174	27	15,52	147	84,48	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Psychiatric disorders	Insomnia	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Psychiatric disorders	Insomnia	16	3	18,75	13	81,25	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Psychiatric disorders	Insomnia	163	28	17,18	135	82,82	NA	NA	NA	1,02	0,60	1,72	0,9552	0,6456
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Psychiatric disorders	Insomnia	173	28	16,18	145	83,82	NA	NA	NA	-	-	-	-	0,6456
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Psychiatric disorders	Insomnia	32	3	9,38	29	90,62	NA	NA	NA	0,70	0,15	3,17	0,6385	0,6456
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Psychiatric disorders	Insomnia	31	4	12,90	27	87,10	NA	NA	NA	-	-	-	-	0,6456
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Psychiatric disorders	Insomnia	18	3	16,67	15	83,33	NA	9,13	NA	0,36	0,07	1,86	0,2018	0,4533
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Psychiatric disorders	Insomnia	17	5	29,41	12	70,59	NA	2,07	NA	-	-	-	-	0,4533

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Psychiatric disorders	Insomnia	61	19	31,15	42	68,85	NA	NA	NA	1,27	0,66	2,46	0,4761	0,4533
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Psychiatric disorders	Insomnia	64	17	26,56	47	73,44	NA	NA	NA	-	-	-	-	0,4533
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Psychiatric disorders	Insomnia	47	4	8,51	43	91,49	NA	NA	NA	1,41	0,29	6,81	0,6640	0,4533
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Psychiatric disorders	Insomnia	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,4533
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Psychiatric disorders	Insomnia	69	5	7,25	64	92,75	NA	NA	NA	0,68	0,21	2,15	0,5085	0,4533
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Psychiatric disorders	Insomnia	70	7	10,00	63	90,00	NA	NA	NA	-	-	-	-	0,4533
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Psychiatric disorders	Insomnia	117	19	16,24	98	83,76	NA	NA	NA	0,98	0,52	1,85	0,9504	0,9487
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Psychiatric disorders	Insomnia	136	21	15,44	115	84,56	NA	NA	NA	-	-	-	-	0,9487
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Psychiatric disorders	Insomnia	78	12	15,38	66	84,62	NA	NA	NA	0,95	0,42	2,15	0,8971	0,9487
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Psychiatric disorders	Insomnia	68	11	16,18	57	83,82	NA	NA	NA	-	-	-	-	0,9487
Patients with at least one AE	Race	Races other than White	SVd Arm	Psychiatric disorders	Insomnia	34	5	14,71	29	85,29	NA	NA	NA	0,50	0,15	1,63	0,2433	0,2172
Patients with at least one AE	Race	Races other than White	Vd Arm	Psychiatric disorders	Insomnia	42	10	23,81	32	76,19	NA	NA	NA	-	-	-	-	0,2172
Patients with at least one AE	Race	White	SVd Arm	Psychiatric disorders	Insomnia	161	26	16,15	135	83,85	NA	NA	NA	1,15	0,65	2,03	0,6423	0,2172
Patients with at least one AE	Race	White	Vd Arm	Psychiatric disorders	Insomnia	162	22	13,58	140	86,42	NA	NA	NA	-	-	-	-	0,2172
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Psychiatric disorders	Insomnia	6	0	0,00	6	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Psychiatric disorders	Insomnia	5	2	40,00	3	60,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Psychiatric disorders	Insomnia	171	25	14,62	146	85,38	NA	NA	NA	0,88	0,51	1,51	0,6405	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Psychiatric disorders	Insomnia	185	29	15,68	156	84,32	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Psychiatric disorders	Insomnia	48	7	14,58	41	85,42	NA	NA	NA	0,72	0,26	2,01	0,5335	0,5230
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Psychiatric disorders	Insomnia	47	8	17,02	39	82,98	NA	NA	NA	-	-	-	-	0,5230
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Psychiatric disorders	Insomnia	147	24	16,33	123	83,67	NA	NA	NA	1,06	0,60	1,87	0,8426	0,5230
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Psychiatric disorders	Insomnia	157	24	15,29	133	84,71	NA	NA	NA	-	-	-	-	0,5230
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Psychiatric disorders	Insomnia	98	16	16,33	82	83,67	NA	NA	NA	0,96	0,49	1,91	0,9176	0,9874

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Psychiatric disorders	Insomnia	104	17	16,35	87	83,65	NA	NA	NA	-	-	-	-	0,9874
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Psychiatric disorders	Insomnia	97	15	15,46	82	84,54	NA	NA	NA	0,97	0,47	2,00	0,9391	0,9874
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Psychiatric disorders	Insomnia	100	15	15,00	85	85,00	NA	NA	NA	-	-	-	-	0,9874
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Psychiatric disorders	Insomnia	98	11	11,22	87	88,78	NA	NA	NA	0,56	0,27	1,19	0,1260	0,0494
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Psychiatric disorders	Insomnia	111	20	18,02	91	81,98	NA	NA	NA	-	-	-	-	0,0494
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Psychiatric disorders	Insomnia	97	20	20,62	77	79,38	NA	NA	NA	1,59	0,77	3,27	0,2020	0,0494
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Psychiatric disorders	Insomnia	93	12	12,90	81	87,10	NA	NA	NA	-	-	-	-	0,0494
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Psychiatric disorders	Insomnia	61	9	14,75	52	85,25	NA	NA	NA	0,99	0,38	2,60	0,9880	0,9954
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Psychiatric disorders	Insomnia	62	9	14,52	53	85,48	NA	NA	NA	-	-	-	-	0,9954
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Psychiatric disorders	Insomnia	134	22	16,42	112	83,58	NA	NA	NA	0,99	0,55	1,78	0,9715	0,9954
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Psychiatric disorders	Insomnia	142	23	16,20	119	83,80	NA	NA	NA	-	-	-	-	0,9954
Patients with at least one AE	total	-	SVd Arm	Injury, poisoning and procedural complications	Fall	195	11	5,64	184	94,36	NA	NA	NA	1,36	0,54	3,41	0,5090	NA
Patients with at least one AE	total	-	Vd Arm	Injury, poisoning and procedural complications	Fall	204	8	3,92	196	96,08	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Infections and infestations	Lower respiratory tract infection	80	6	7,50	74	92,50	NA	NA	NA	5,02	0,60	42,35	0,1010	0,1130
Patients with at least one AE	Gender	Female	Vd Arm	Infections and infestations	Lower respiratory tract infection	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,1130
Patients with at least one AE	Gender	Male	SVd Arm	Infections and infestations	Lower respiratory tract infection	115	8	6,96	107	93,04	NA	NA	NA	0,75	0,28	2,00	0,5695	0,1130
Patients with at least one AE	Gender	Male	Vd Arm	Infections and infestations	Lower respiratory tract infection	113	10	8,85	103	91,15	NA	NA	NA	-	-	-	-	0,1130
Patients with at least one AE	Age Group	<65	SVd Arm	Infections and infestations	Lower respiratory tract infection	86	6	6,98	80	93,02	NA	NA	NA	2,33	0,46	11,76	0,2923	0,3601
Patients with at least one AE	Age Group	<65	Vd Arm	Infections and infestations	Lower respiratory tract infection	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,3601

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	>=65	SVd Arm	Infections and infestations	Lower respiratory tract infection	109	8	7,34	101	92,66	NA	NA	NA	0,96	0,35	2,60	0,9355	0,3601
Patients with at least one AE	Age Group	>=65	Vd Arm	Infections and infestations	Lower respiratory tract infection	129	9	6,98	120	93,02	NA	NA	NA	-	-	-	-	0,3601
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Lower respiratory tract infection	173	11	6,36	162	93,64	NA	NA	NA	1,01	0,41	2,51	0,9796	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Lower respiratory tract infection	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Lower respiratory tract infection	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Lower respiratory tract infection	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Lower respiratory tract infection	163	13	7,98	150	92,02	NA	NA	NA	1,10	0,48	2,49	0,8279	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Lower respiratory tract infection	173	11	6,36	162	93,64	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Lower respiratory tract infection	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Lower respiratory tract infection	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Lower respiratory tract infection	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,5117
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Lower respiratory tract infection	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	0,5117
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Lower respiratory tract infection	61	8	13,11	53	86,89	NA	NA	NA	1,12	0,42	2,99	0,8284	0,5117
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Lower respiratory tract infection	64	8	12,50	56	87,50	NA	NA	NA	-	-	-	-	0,5117
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Lower respiratory tract infection	47	4	8,51	43	91,49	NA	NA	NA	3,39	0,37	30,65	0,2491	0,5117
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Lower respiratory tract infection	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,5117
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Lower respiratory tract infection	69	2	2,90	67	97,10	NA	NA	NA	0,52	0,05	5,74	0,5873	0,5117
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Lower respiratory tract infection	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,5117
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Lower respiratory tract infection	117	11	9,40	106	90,60	NA	NA	NA	1,56	0,60	4,08	0,3559	0,2401
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Lower respiratory tract infection	136	7	5,15	129	94,85	NA	NA	NA	-	-	-	-	0,2401
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Lower respiratory tract infection	78	3	3,85	75	96,15	NA	NA	NA	0,48	0,09	2,67	0,3948	0,2401
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Lower respiratory tract infection	68	4	5,88	64	94,12	NA	NA	NA	-	-	-	-	0,2401

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	Races other than White	SVd Arm	Infections and infestations	Lower respiratory tract infection	34	3	8,82	31	91,18	NA	17,28	NA	1,02	0,09	11,43	0,9860	0,9292
Patients with at least one AE	Race	Races other than White	Vd Arm	Infections and infestations	Lower respiratory tract infection	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,9292
Patients with at least one AE	Race	White	SVd Arm	Infections and infestations	Lower respiratory tract infection	161	11	6,83	150	93,17	NA	NA	NA	1,15	0,47	2,78	0,7594	0,9292
Patients with at least one AE	Race	White	Vd Arm	Infections and infestations	Lower respiratory tract infection	162	9	5,56	153	94,44	NA	NA	NA	-	-	-	-	0,9292
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Lower respiratory tract infection	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Lower respiratory tract infection	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Lower respiratory tract infection	171	12	7,02	159	92,98	NA	NA	NA	1,50	0,60	3,77	0,3810	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Lower respiratory tract infection	185	8	4,32	177	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Infections and infestations	Lower respiratory tract infection	48	3	6,25	45	93,75	NA	NA	NA	0,67	0,15	3,01	0,6011	0,3599
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Infections and infestations	Lower respiratory tract infection	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,3599
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Infections and infestations	Lower respiratory tract infection	147	11	7,48	136	92,52	NA	NA	NA	1,55	0,59	4,08	0,3739	0,3599
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Infections and infestations	Lower respiratory tract infection	157	7	4,46	150	95,54	NA	NA	NA	-	-	-	-	0,3599
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Lower respiratory tract infection	98	5	5,10	93	94,90	NA	NA	NA	1,30	0,29	5,80	0,7329	0,9144
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Lower respiratory tract infection	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,9144
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Lower respiratory tract infection	97	9	9,28	88	90,72	NA	NA	NA	1,18	0,45	3,07	0,7391	0,9144
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Lower respiratory tract infection	100	8	8,00	92	92,00	NA	NA	NA	-	-	-	-	0,9144
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Lower respiratory tract infection	98	6	6,12	92	93,88	NA	NA	NA	1,24	0,35	4,38	0,7389	0,9906
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Lower respiratory tract infection	111	5	4,50	106	95,50	NA	NA	NA	-	-	-	-	0,9906
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Lower respiratory tract infection	97	8	8,25	89	91,75	NA	NA	NA	1,25	0,43	3,63	0,6795	0,9906

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Lower respiratory tract infection	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,9906
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Lower respiratory tract infection	61	4	6,56	57	93,44	NA	NA	NA	0,96	0,24	3,88	0,9577	0,7124
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Lower respiratory tract infection	62	4	6,45	58	93,55	NA	NA	NA	-	-	-	-	0,7124
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Lower respiratory tract infection	134	10	7,46	124	92,54	NA	NA	NA	1,33	0,49	3,58	0,5735	0,7124
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Lower respiratory tract infection	142	7	4,93	135	95,07	NA	NA	NA	-	-	-	-	0,7124
Patients with at least one AE	total	-	SVd Arm	Injury, poisoning and procedural complications	Overdose	195	10	5,13	185	94,87	-	-	-	-	-	-	-	NA
Patients with at least one AE	total	-	Vd Arm	Injury, poisoning and procedural complications	Overdose	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	80	5	6,25	75	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Female	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Male	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	115	5	4,35	110	95,65	NA	NA	NA	2,36	0,45	12,30	0,2955	NA
Patients with at least one AE	Gender	Male	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	86	6	6,98	80	93,02	NA	NA	NA	2,19	0,42	11,41	0,3406	NA
Patients with at least one AE	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	109	4	3,67	105	96,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	173	7	4,05	166	95,95	NA	NA	NA	2,54	0,51	12,65	0,2396	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	163	8	4,91	155	95,09	NA	NA	NA	3,54	0,74	16,93	0,0923	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	173	2	1,16	171	98,84	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	61	5	8,20	56	91,80	NA	NA	NA	2,47	0,48	12,76	0,2631	NA
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	47	1	2,13	46	97,87	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	69	3	4,35	66	95,65	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	117	7	5,98	110	94,02	NA	NA	NA	3,83	0,79	18,48	0,0722	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	78	3	3,85	75	96,15	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	34	2	5,88	32	94,12	NA	NA	NA	3,07	0,18	53,36	0,4202	0,7345
Patients with at least one AE	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,7345
Patients with at least one AE	Race	White	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	161	8	4,97	153	95,03	NA	NA	NA	5,67	0,69	46,45	0,0692	0,7345
Patients with at least one AE	Race	White	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	162	1	0,62	161	99,38	NA	NA	NA	-	-	-	-	0,7345
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	171	9	5,26	162	94,74	NA	NA	NA	3,94	0,83	18,74	0,0646	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	185	2	1,08	183	98,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	48	2	4,17	46	95,83	NA	NA	NA	0,70	0,05	9,83	0,7919	0,1509
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,1509
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	147	8	5,44	139	94,56	NA	NA	NA	8,24	1,03	66,07	0,0177	0,1509
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,1509
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	98	5	5,10	93	94,90	NA	NA	NA	2,41	0,47	12,42	0,2782	NA
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	97	5	5,15	92	94,85	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	98	7	7,14	91	92,86	NA	NA	NA	3,34	0,64	17,33	0,1280	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	97	3	3,09	94	96,91	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	61	2	3,28	59	96,72	NA	NA	NA	0,70	0,05	9,83	0,7919	0,1520
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,1520
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	Lymphopenia	134	8	5,97	126	94,03	NA	NA	NA	8,18	1,02	65,59	0,0182	0,1520
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	Lymphopenia	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	0,1520

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	total	-	SVd Arm	Injury, poisoning and procedural complications	-	195	41	21,03	154	78,97	NA	NA	NA	1,86	1,12	3,09	0,0145	NA
Patients with at least one AE	total	-	Vd Arm	Injury, poisoning and procedural complications	-	204	24	11,76	180	88,24	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	80	2	2,50	78	97,50	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Female	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	91	3	3,30	88	96,70	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Male	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	115	5	4,35	110	95,65	NA	NA	NA	0,50	0,17	1,50	0,2060	NA
Patients with at least one AE	Gender	Male	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Age Group	<65	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	86	6	6,98	80	93,02	NA	NA	NA	0,22	0,06	0,84	0,0153	0,7611
Patients with at least one AE	Age Group	<65	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,7611
Patients with at least one AE	Age Group	>=65	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	109	1	0,92	108	99,08	NA	NA	NA	0,33	0,04	2,96	0,2961	0,7611
Patients with at least one AE	Age Group	>=65	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	129	4	3,10	125	96,90	NA	NA	NA	-	-	-	-	0,7611
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	173	7	4,05	166	95,95	NA	NA	NA	0,53	0,19	1,44	0,2059	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	174	10	5,75	164	94,25	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	163	6	3,68	157	96,32	NA	NA	NA	0,38	0,14	1,08	0,0608	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	173	12	6,94	161	93,06	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	18	2	11,11	16	88,89	NA	26,58	NA	0,23	0,03	2,09	0,1555	0,6317
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	17	4	23,53	13	76,47	NA	9,40	NA	-	-	-	-	0,6317
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	61	2	3,28	59	96,72	NA	NA	NA	0,60	0,11	3,28	0,5475	0,6317
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,6317
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	47	0	0,00	47	100,00	-	-	-	-	-	-	-	0,6317
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	53	2	3,77	51	96,23	-	-	-	-	-	-	-	0,6317
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	69	3	4,35	66	95,65	NA	NA	NA	0,93	0,15	6,00	0,9419	0,6317
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,6317
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	117	4	3,42	113	96,58	NA	NA	NA	0,46	0,14	1,51	0,1894	0,8123
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	136	9	6,62	127	93,38	NA	NA	NA	-	-	-	-	0,8123
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	78	3	3,85	75	96,15	NA	NA	NA	0,59	0,11	3,09	0,5287	0,8123
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,8123
Patients with at least one AE	Race	Races other than White	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	34	0	0,00	34	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	42	5	11,90	37	88,10	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	161	7	4,35	154	95,65	NA	NA	NA	0,69	0,23	2,06	0,5091	NA
Patients with at least one AE	Race	White	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	162	7	4,32	155	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	171	5	2,92	166	97,08	NA	NA	NA	0,38	0,12	1,17	0,0813	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	185	10	5,41	175	94,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	48	2	4,17	46	95,83	NA	NA	NA	0,38	0,04	3,45	0,3783	0,8469
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,8469
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	147	5	3,40	142	96,60	NA	NA	NA	0,48	0,16	1,41	0,1715	0,8469
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	157	10	6,37	147	93,63	NA	NA	NA	-	-	-	-	0,8469
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	98	2	2,04	96	97,96	NA	NA	NA	0,39	0,08	2,03	0,2488	0,8225
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,8225
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	97	5	5,15	92	94,85	NA	NA	NA	0,50	0,15	1,70	0,2573	0,8225
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	100	7	7,00	93	93,00	NA	NA	NA	-	-	-	-	0,8225
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	98	4	4,08	94	95,92	NA	NA	NA	0,44	0,11	1,73	0,2265	0,9214

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	111	7	6,31	104	93,69	NA	NA	NA	-	-	-	-	0,9214
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	97	3	3,09	94	96,91	NA	NA	NA	0,48	0,11	2,07	0,3177	0,9214
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,9214
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	61	2	3,28	59	96,72	NA	NA	NA	0,28	0,04	2,12	0,2049	0,6184
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,6184
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	134	5	3,73	129	96,27	NA	NA	NA	0,51	0,17	1,52	0,2166	0,6184
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	142	9	6,34	133	93,66	NA	NA	NA	-	-	-	-	0,6184
Patients with at least one AE	total	-	SVd Arm	Investigations	Alanine aminotransferase increased	195	13	6,67	182	93,33	NA	NA	NA	1,95	0,77	4,91	0,1496	NA
Patients with at least one AE	total	-	Vd Arm	Investigations	Alanine aminotransferase increased	204	7	3,43	197	96,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Infections and infestations	Nasopharyngitis	80	10	12,50	70	87,50	NA	NA	NA	2,37	0,79	7,13	0,1147	0,7015
Patients with at least one AE	Gender	Female	Vd Arm	Infections and infestations	Nasopharyngitis	91	6	6,59	85	93,41	NA	39,36	NA	-	-	-	-	0,7015
Patients with at least one AE	Gender	Male	SVd Arm	Infections and infestations	Nasopharyngitis	115	13	11,30	102	88,70	NA	NA	NA	3,19	1,12	9,09	0,0224	0,7015
Patients with at least one AE	Gender	Male	Vd Arm	Infections and infestations	Nasopharyngitis	113	5	4,42	108	95,58	NA	NA	NA	-	-	-	-	0,7015
Patients with at least one AE	Age Group	<65	SVd Arm	Infections and infestations	Nasopharyngitis	86	13	15,12	73	84,88	NA	NA	NA	2,86	0,97	8,44	0,0488	0,8092
Patients with at least one AE	Age Group	<65	Vd Arm	Infections and infestations	Nasopharyngitis	75	5	6,67	70	93,33	NA	NA	NA	-	-	-	-	0,8092
Patients with at least one AE	Age Group	>=65	SVd Arm	Infections and infestations	Nasopharyngitis	109	10	9,17	99	90,83	NA	NA	NA	2,37	0,80	7,04	0,1114	0,8092
Patients with at least one AE	Age Group	>=65	Vd Arm	Infections and infestations	Nasopharyngitis	129	6	4,65	123	95,35	NA	39,36	NA	-	-	-	-	0,8092
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Nasopharyngitis	173	20	11,56	153	88,44	NA	NA	NA	2,14	0,96	4,73	0,0558	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Nasopharyngitis	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Nasopharyngitis	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Nasopharyngitis	16	1	6,25	15	93,75	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Nasopharyngitis	163	20	12,27	143	87,73	NA	NA	NA	2,00	0,92	4,31	0,0729	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Nasopharyngitis	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Nasopharyngitis	32	3	9,38	29	90,62	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Nasopharyngitis	31	1	3,23	30	96,77	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Nasopharyngitis	18	4	22,22	14	77,78	9,92	7,89	NA	3,44	0,34	34,64	0,2690	0,5402
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Nasopharyngitis	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,5402
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Nasopharyngitis	61	6	9,84	55	90,16	NA	25,00	NA	1,17	0,35	3,83	0,8001	0,5402
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Nasopharyngitis	64	6	9,38	58	90,62	39,36	39,36	NA	-	-	-	-	0,5402
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Nasopharyngitis	47	3	6,38	44	93,62	-	-	-	-	-	-	-	0,5402
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Nasopharyngitis	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,5402
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Nasopharyngitis	69	10	14,49	59	85,51	NA	NA	NA	2,68	0,83	8,61	0,0856	0,5402
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Nasopharyngitis	70	4	5,71	66	94,29	NA	NA	NA	-	-	-	-	0,5402
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Nasopharyngitis	117	13	11,11	104	88,89	NA	NA	NA	2,51	0,88	7,14	0,0739	0,7780
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Nasopharyngitis	136	6	4,41	130	95,59	NA	39,36	NA	-	-	-	-	0,7780
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Nasopharyngitis	78	10	12,82	68	87,18	NA	NA	NA	2,02	0,67	6,08	0,2030	0,7780
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Nasopharyngitis	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,7780
Patients with at least one AE	Race	Races other than White	SVd Arm	Infections and infestations	Nasopharyngitis	34	8	23,53	26	76,47	NA	11,70	NA	4,46	1,25	15,91	0,0140	0,3676
Patients with at least one AE	Race	Races other than White	Vd Arm	Infections and infestations	Nasopharyngitis	42	4	9,52	38	90,48	NA	NA	NA	-	-	-	-	0,3676
Patients with at least one AE	Race	White	SVd Arm	Infections and infestations	Nasopharyngitis	161	15	9,32	146	90,68	NA	NA	NA	2,14	0,82	5,58	0,1112	0,3676
Patients with at least one AE	Race	White	Vd Arm	Infections and infestations	Nasopharyngitis	162	7	4,32	155	95,68	NA	39,36	NA	-	-	-	-	0,3676
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Nasopharyngitis	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Nasopharyngitis	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Nasopharyngitis	171	20	11,70	151	88,30	NA	NA	NA	2,58	1,17	5,72	0,0156	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Nasopharyngitis	185	10	5,41	175	94,59	NA	39,36	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Infections and infestations	Nasopharyngitis	48	4	8,33	44	91,67	NA	NA	NA	3,30	0,37	29,83	0,2599	0,7871
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Infections and infestations	Nasopharyngitis	47	2	4,26	45	95,74	39,36	NA	NA	-	-	-	-	0,7871
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Infections and infestations	Nasopharyngitis	147	19	12,93	128	87,07	NA	NA	NA	2,39	1,08	5,32	0,0275	0,7871
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Infections and infestations	Nasopharyngitis	157	9	5,73	148	94,27	NA	NA	NA	-	-	-	-	0,7871
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Nasopharyngitis	98	8	8,16	90	91,84	NA	NA	NA	1,60	0,52	4,95	0,4061	0,3302
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Nasopharyngitis	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,3302
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Nasopharyngitis	97	15	15,46	82	84,54	NA	NA	NA	3,41	1,23	9,46	0,0123	0,3302
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Nasopharyngitis	100	6	6,00	94	94,00	NA	39,36	NA	-	-	-	-	0,3302
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Nasopharyngitis	98	11	11,22	87	88,78	NA	NA	NA	3,05	1,04	8,88	0,0325	0,5548
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Nasopharyngitis	111	5	4,50	106	95,50	NA	NA	NA	-	-	-	-	0,5548
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Nasopharyngitis	97	12	12,37	85	87,63	NA	NA	NA	1,94	0,68	5,53	0,2072	0,5548
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Nasopharyngitis	93	6	6,45	87	93,55	39,36	NA	NA	-	-	-	-	0,5548
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Nasopharyngitis	61	5	8,20	56	91,80	NA	NA	NA	3,30	0,37	29,83	0,2599	0,7555
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Nasopharyngitis	62	2	3,23	60	96,77	39,36	39,36	NA	-	-	-	-	0,7555
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Nasopharyngitis	134	18	13,43	116	86,57	NA	NA	NA	2,28	1,02	5,10	0,0403	0,7555

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Nasopharyngitis	142	9	6,34	133	93,66	NA	NA	NA	-	-	-	-	0,7555
Patients with at least one AE	total	-	SVd Arm	Investigations	Aspartate aminotransferase increased	195	10	5,13	185	94,87	NA	NA	NA	1,89	0,68	5,23	0,2160	NA
Patients with at least one AE	total	-	Vd Arm	Investigations	Aspartate aminotransferase increased	204	6	2,94	198	97,06	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Gastrointestinal disorders	Nausea	80	46	57,50	34	42,50	2,99	1,45	NA	7,41	3,60	15,28	0,0000	0,8639
Patients with at least one AE	Gender	Female	Vd Arm	Gastrointestinal disorders	Nausea	91	11	12,09	80	87,91	NA	NA	NA	-	-	-	-	0,8639
Patients with at least one AE	Gender	Male	SVd Arm	Gastrointestinal disorders	Nausea	115	52	45,22	63	54,78	17,28	3,94	NA	6,79	3,43	13,48	0,0000	0,8639
Patients with at least one AE	Gender	Male	Vd Arm	Gastrointestinal disorders	Nausea	113	10	8,85	103	91,15	NA	NA	NA	-	-	-	-	0,8639
Patients with at least one AE	Age Group	<65	SVd Arm	Gastrointestinal disorders	Nausea	86	41	47,67	45	52,33	NA	2,17	NA	5,53	2,57	11,92	0,0000	0,4251
Patients with at least one AE	Age Group	<65	Vd Arm	Gastrointestinal disorders	Nausea	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,4251
Patients with at least one AE	Age Group	>=65	SVd Arm	Gastrointestinal disorders	Nausea	109	57	52,29	52	47,71	4,47	1,87	NA	8,33	4,35	15,95	0,0000	0,4251
Patients with at least one AE	Age Group	>=65	Vd Arm	Gastrointestinal disorders	Nausea	129	13	10,08	116	89,92	NA	NA	NA	-	-	-	-	0,4251
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Nausea	173	88	50,87	85	49,13	4,60	2,56	NA	6,22	3,78	10,25	0,0000	0,9801
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Nausea	174	19	10,92	155	89,08	NA	NA	NA	-	-	-	-	0,9801
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Nausea	12	5	41,67	7	58,33	NA	1,05	NA	6,40	0,71	58,14	0,0648	0,9801
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Nausea	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,9801
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Nausea	163	91	55,83	72	44,17	3,94	1,68	17,28	7,77	4,62	13,08	0,0000	0,4945
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Nausea	173	19	10,98	154	89,02	NA	NA	NA	-	-	-	-	0,4945
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Nausea	32	7	21,88	25	78,12	NA	NA	NA	4,32	0,87	21,44	0,0530	0,4945
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Nausea	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,4945
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	Nausea	18	14	77,78	4	22,22	0,10	0,07	NA	17,12	2,20	133,11	0,0003	0,6751
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	Nausea	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,6751
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	Nausea	61	34	55,74	27	44,26	2,10	0,16	NA	5,51	2,61	11,63	0,0000	0,6751
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	Nausea	64	9	14,06	55	85,94	NA	NA	NA	-	-	-	-	0,6751

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	Nausea	47	17	36,17	30	63,83	NA	17,28	NA	10,12	2,32	44,03	0,0001	0,6751
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	Nausea	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,6751
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	Nausea	69	33	47,83	36	52,17	8,31	2,56	NA	5,57	2,56	12,11	0,0000	0,6751
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	Nausea	70	8	11,43	62	88,57	NA	32,53	NA	-	-	-	-	0,6751
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	Nausea	117	57	48,72	60	51,28	8,31	3,94	NA	6,32	3,44	11,58	0,0000	0,9611
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	Nausea	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,9611
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	Nausea	78	41	52,56	37	47,44	3,35	1,64	NA	6,16	2,88	13,21	0,0000	0,9611
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	Nausea	68	8	11,76	60	88,24	NA	32,53	NA	-	-	-	-	0,9611
Patients with at least one AE	Race	Races other than White	SVd Arm	Gastrointestinal disorders	Nausea	34	20	58,82	14	41,18	2,00	1,05	NA	11,01	3,58	33,90	0,0000	0,4032
Patients with at least one AE	Race	Races other than White	Vd Arm	Gastrointestinal disorders	Nausea	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,4032
Patients with at least one AE	Race	White	SVd Arm	Gastrointestinal disorders	Nausea	161	78	48,45	83	51,55	9,26	3,94	NA	6,46	3,76	11,12	0,0000	0,4032
Patients with at least one AE	Race	White	Vd Arm	Gastrointestinal disorders	Nausea	162	16	9,88	146	90,12	NA	NA	NA	-	-	-	-	0,4032
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Nausea	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Nausea	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Nausea	171	86	50,29	85	49,71	6,01	2,56	NA	6,53	3,96	10,77	0,0000	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Nausea	185	20	10,81	165	89,19	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	Nausea	48	25	52,08	23	47,92	3,98	1,68	NA	6,68	2,53	17,62	0,0000	0,9765
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	Nausea	47	5	10,64	42	89,36	NA	32,53	NA	-	-	-	-	0,9765
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	Nausea	147	73	49,66	74	50,34	6,01	2,10	NA	6,57	3,82	11,31	0,0000	0,9765

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	Nausea	157	16	10,19	141	89,81	NA	NA	NA	-	-	-	-	0,9765
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	Nausea	98	49	50,00	49	50,00	8,31	2,00	NA	7,87	3,85	16,07	0,0000	0,4970
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	Nausea	104	9	8,65	95	91,35	NA	NA	NA	-	-	-	-	0,4970
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	Nausea	97	49	50,52	48	49,48	4,04	2,79	NA	5,65	2,99	10,67	0,0000	0,4970
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	Nausea	100	12	12,00	88	88,00	NA	NA	NA	-	-	-	-	0,4970
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	Nausea	98	47	47,96	51	52,04	17,28	2,56	NA	5,26	2,88	9,63	0,0000	0,1861
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	Nausea	111	14	12,61	97	87,39	NA	NA	NA	-	-	-	-	0,1861
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	Nausea	97	51	52,58	46	47,42	4,47	1,87	NA	10,63	4,55	24,87	0,0000	0,1861
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	Nausea	93	7	7,53	86	92,47	NA	32,53	NA	-	-	-	-	0,1861
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	Nausea	61	31	50,82	30	49,18	4,04	1,68	NA	6,06	2,64	13,92	0,0000	0,8087
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	Nausea	62	7	11,29	55	88,71	NA	32,53	NA	-	-	-	-	0,8087
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	Nausea	134	67	50,00	67	50,00	6,01	2,10	NA	6,87	3,85	12,26	0,0000	0,8087
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	Nausea	142	14	9,86	128	90,14	NA	NA	NA	-	-	-	-	0,8087
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Gastrointestinal disorders	Nausea	195	15	7,69	180	92,31	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Gastrointestinal disorders	Nausea	204	0	0,00	204	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Gastrointestinal disorders	Nausea	80	8	10,00	72	90,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Gastrointestinal disorders	Nausea	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Gastrointestinal disorders	Nausea	115	7	6,09	108	93,91	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Gastrointestinal disorders	Nausea	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Gastrointestinal disorders	Nausea	86	2	2,33	84	97,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Gastrointestinal disorders	Nausea	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Gastrointestinal disorders	Nausea	109	13	11,93	96	88,07	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Gastrointestinal disorders	Nausea	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Nausea	173	13	7,51	160	92,49	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Nausea	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Nausea	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Nausea	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Nausea	163	13	7,98	150	92,02	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Nausea	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Nausea	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Nausea	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	Nausea	18	3	16,67	15	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	Nausea	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	Nausea	61	6	9,84	55	90,16	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	Nausea	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	Nausea	47	2	4,26	45	95,74	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	Nausea	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	Nausea	69	4	5,80	65	94,20	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	Nausea	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	Nausea	117	9	7,69	108	92,31	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	Nausea	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	Nausea	78	6	7,69	72	92,31	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	Nausea	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Gastrointestinal disorders	Nausea	34	3	8,82	31	91,18	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Gastrointestinal disorders	Nausea	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Gastrointestinal disorders	Nausea	161	12	7,45	149	92,55	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Gastrointestinal disorders	Nausea	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Nausea	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Nausea	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Nausea	171	13	7,60	158	92,40	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Nausea	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	Nausea	48	4	8,33	44	91,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	Nausea	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	Nausea	147	11	7,48	136	92,52	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	Nausea	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	Nausea	98	9	9,18	89	90,82	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	Nausea	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	Nausea	97	6	6,19	91	93,81	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	Nausea	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	Nausea	98	8	8,16	90	91,84	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	Nausea	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	Nausea	97	7	7,22	90	92,78	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	Nausea	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	Nausea	61	5	8,20	56	91,80	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	Nausea	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	Nausea	134	10	7,46	124	92,54	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	Nausea	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Investigations	Blood creatinine increased	195	11	5,64	184	94,36	NA	NA	NA	1,82	0,70	4,71	0,2115	NA
Patients with at least one AE	total	-	Vd Arm	Investigations	Blood creatinine increased	204	7	3,43	197	96,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Nervous system disorders	Neuropathy peripheral	80	18	22,50	62	77,50	37,98	37,98	NA	0,57	0,31	1,07	0,0752	0,7248
Patients with at least one AE	Gender	Female	Vd Arm	Nervous system disorders	Neuropathy peripheral	91	26	28,57	65	71,43	NA	NA	NA	-	-	-	-	0,7248
Patients with at least one AE	Gender	Male	SVd Arm	Nervous system disorders	Neuropathy peripheral	115	20	17,39	95	82,61	NA	NA	NA	0,49	0,28	0,86	0,0105	0,7248
Patients with at least one AE	Gender	Male	Vd Arm	Nervous system disorders	Neuropathy peripheral	113	35	30,97	78	69,03	NA	20,96	NA	-	-	-	-	0,7248
Patients with at least one AE	Age Group	<65	SVd Arm	Nervous system disorders	Neuropathy peripheral	86	15	17,44	71	82,56	NA	NA	NA	0,40	0,21	0,79	0,0059	0,2863
Patients with at least one AE	Age Group	<65	Vd Arm	Nervous system disorders	Neuropathy peripheral	75	24	32,00	51	68,00	NA	NA	NA	-	-	-	-	0,2863
Patients with at least one AE	Age Group	>=65	SVd Arm	Nervous system disorders	Neuropathy peripheral	109	23	21,10	86	78,90	NA	37,98	NA	0,64	0,38	1,10	0,1032	0,2863
Patients with at least one AE	Age Group	>=65	Vd Arm	Nervous system disorders	Neuropathy peripheral	129	37	28,68	92	71,32	NA	20,96	NA	-	-	-	-	0,2863
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Neuropathy peripheral	173	36	20,81	137	79,19	NA	37,98	NA	0,58	0,37	0,89	0,0119	0,5986
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Neuropathy peripheral	174	52	29,89	122	70,11	NA	NA	NA	-	-	-	-	0,5986
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	Neuropathy peripheral	12	1	8,33	11	91,67	NA	7,10	NA	0,29	0,02	3,54	0,3110	0,5986
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	Neuropathy peripheral	16	4	25,00	12	75,00	NA	7,56	NA	-	-	-	-	0,5986
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Neuropathy peripheral	163	35	21,47	128	78,53	NA	37,98	NA	0,59	0,38	0,92	0,0175	0,3104
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Neuropathy peripheral	173	53	30,64	120	69,36	NA	NA	NA	-	-	-	-	0,3104
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	Neuropathy peripheral	32	3	9,38	29	90,62	NA	NA	NA	0,28	0,07	1,12	0,0588	0,3104
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	Neuropathy peripheral	31	8	25,81	23	74,19	NA	NA	NA	-	-	-	-	0,3104
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	Neuropathy peripheral	18	2	11,11	16	88,89	NA	9,95	NA	0,32	0,06	1,71	0,1623	0,9212
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	Neuropathy peripheral	17	6	35,29	11	64,71	NA	2,89	NA	-	-	-	-	0,9212
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	Neuropathy peripheral	61	17	27,87	44	72,13	NA	8,08	NA	0,59	0,32	1,10	0,0926	0,9212
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	Neuropathy peripheral	64	26	40,62	38	59,38	20,96	4,34	NA	-	-	-	-	0,9212
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	Neuropathy peripheral	47	9	19,15	38	80,85	NA	37,98	NA	0,61	0,24	1,54	0,2946	0,9212

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	Neuropathy peripheral	53	12	22,64	41	77,36	NA	NA	NA	-	-	-	-	0,9212
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	Neuropathy peripheral	69	10	14,49	59	85,51	NA	NA	NA	0,57	0,26	1,25	0,1565	0,9212
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	Neuropathy peripheral	70	17	24,29	53	75,71	NA	NA	NA	-	-	-	-	0,9212
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	Neuropathy peripheral	117	24	20,51	93	79,49	NA	37,98	NA	0,51	0,30	0,85	0,0090	0,5903
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	Neuropathy peripheral	136	42	30,88	94	69,12	NA	20,96	NA	-	-	-	-	0,5903
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	Neuropathy peripheral	78	14	17,95	64	82,05	NA	NA	NA	0,64	0,32	1,29	0,2112	0,5903
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	Neuropathy peripheral	68	19	27,94	49	72,06	NA	NA	NA	-	-	-	-	0,5903
Patients with at least one AE	Race	Races other than White	SVd Arm	Nervous system disorders	Neuropathy peripheral	34	8	23,53	26	76,47	NA	NA	NA	0,42	0,17	1,01	0,0461	0,5180
Patients with at least one AE	Race	Races other than White	Vd Arm	Nervous system disorders	Neuropathy peripheral	42	20	47,62	22	52,38	20,96	3,45	NA	-	-	-	-	0,5180
Patients with at least one AE	Race	White	SVd Arm	Nervous system disorders	Neuropathy peripheral	161	30	18,63	131	81,37	NA	37,98	NA	0,58	0,36	0,94	0,0255	0,5180
Patients with at least one AE	Race	White	Vd Arm	Nervous system disorders	Neuropathy peripheral	162	41	25,31	121	74,69	NA	NA	NA	-	-	-	-	0,5180
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Neuropathy peripheral	6	2	33,33	4	66,67	NA	5,55	NA	0,27	0,02	3,04	0,2593	0,5942
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Neuropathy peripheral	5	2	40,00	3	60,00	NA	4,14	NA	-	-	-	-	0,5942
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Neuropathy peripheral	171	30	17,54	141	82,46	NA	NA	NA	0,53	0,34	0,84	0,0057	0,5942
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Neuropathy peripheral	185	52	28,11	133	71,89	NA	NA	NA	-	-	-	-	0,5942
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Nervous system disorders	Neuropathy peripheral	48	11	22,92	37	77,08	37,98	37,98	NA	0,76	0,32	1,80	0,5274	0,3945
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Nervous system disorders	Neuropathy peripheral	47	11	23,40	36	76,60	NA	NA	NA	-	-	-	-	0,3945
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Nervous system disorders	Neuropathy peripheral	147	27	18,37	120	81,63	NA	NA	NA	0,49	0,31	0,79	0,0027	0,3945
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Nervous system disorders	Neuropathy peripheral	157	50	31,85	107	68,15	NA	20,96	NA	-	-	-	-	0,3945

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	Neuropathy peripheral	98	17	17,35	81	82,65	NA	37,98	NA	0,58	0,31	1,09	0,0842	0,7978
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	Neuropathy peripheral	104	25	24,04	79	75,96	NA	NA	NA	-	-	-	-	0,7978
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	Neuropathy peripheral	97	21	21,65	76	78,35	NA	NA	NA	0,52	0,30	0,89	0,0158	0,7978
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	Neuropathy peripheral	100	36	36,00	64	64,00	NA	14,36	NA	-	-	-	-	0,7978
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	Neuropathy peripheral	98	17	17,35	81	82,65	NA	37,98	NA	0,47	0,26	0,86	0,0121	0,5391
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	Neuropathy peripheral	111	34	30,63	77	69,37	NA	20,96	NA	-	-	-	-	0,5391
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	Neuropathy peripheral	97	21	21,65	76	78,35	NA	NA	NA	0,61	0,34	1,09	0,0923	0,5391
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	Neuropathy peripheral	93	27	29,03	66	70,97	NA	NA	NA	-	-	-	-	0,5391
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	Neuropathy peripheral	61	13	21,31	48	78,69	NA	37,98	NA	0,70	0,33	1,50	0,3602	0,4529
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	Neuropathy peripheral	62	16	25,81	46	74,19	NA	NA	NA	-	-	-	-	0,4529
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	Neuropathy peripheral	134	25	18,66	109	81,34	NA	NA	NA	0,50	0,30	0,81	0,0044	0,4529
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	Neuropathy peripheral	142	45	31,69	97	68,31	NA	20,96	NA	-	-	-	-	0,4529
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Nervous system disorders	Neuropathy peripheral	195	6	3,08	189	96,92	NA	NA	NA	0,45	0,17	1,18	0,0969	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Nervous system disorders	Neuropathy peripheral	204	13	6,37	191	93,63	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Nervous system disorders	Neuropathy peripheral	80	4	5,00	76	95,00	NA	NA	NA	1,02	0,25	4,17	0,9785	0,1241
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Nervous system disorders	Neuropathy peripheral	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,1241
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Nervous system disorders	Neuropathy peripheral	115	2	1,74	113	98,26	NA	NA	NA	0,20	0,04	0,92	0,0219	0,1241

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Nervous system disorders	Neuropathy peripheral	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	0,1241
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Nervous system disorders	Neuropathy peripheral	86	2	2,33	84	97,67	NA	NA	NA	0,72	0,10	5,19	0,7431	0,6072
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Nervous system disorders	Neuropathy peripheral	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,6072
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Nervous system disorders	Neuropathy peripheral	109	4	3,67	105	96,33	NA	NA	NA	0,39	0,12	1,25	0,1030	0,6072
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Nervous system disorders	Neuropathy peripheral	129	11	8,53	118	91,47	NA	NA	NA	-	-	-	-	0,6072
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Neuropathy peripheral	173	6	3,47	167	96,53	NA	NA	NA	0,60	0,21	1,68	0,3238	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Neuropathy peripheral	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	Neuropathy peripheral	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	Neuropathy peripheral	16	2	12,50	14	87,50	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Neuropathy peripheral	163	5	3,07	158	96,93	NA	NA	NA	0,55	0,18	1,65	0,2811	0,9125
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Neuropathy peripheral	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	0,9125
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	Neuropathy peripheral	32	1	3,12	31	96,88	NA	NA	NA	0,47	0,04	5,68	0,5485	0,9125
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	Neuropathy peripheral	31	3	9,68	28	90,32	NA	16,76	NA	-	-	-	-	0,9125
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	Neuropathy peripheral	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,7051
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	Neuropathy peripheral	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	0,7051
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	Neuropathy peripheral	61	2	3,28	59	96,72	NA	NA	NA	0,30	0,06	1,45	0,1112	0,7051

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	Neuropathy peripheral	64	7	10,94	57	89,06	NA	NA	NA	-	-	-	-	0,7051
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	Neuropathy peripheral	47	3	6,38	44	93,62	NA	NA	NA	0,74	0,14	3,80	0,7128	0,7051
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	Neuropathy peripheral	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,7051
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	Neuropathy peripheral	69	1	1,45	68	98,55	NA	NA	NA	0,71	0,06	8,64	0,7880	0,7051
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	Neuropathy peripheral	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,7051
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	Neuropathy peripheral	117	4	3,42	113	96,58	NA	NA	NA	0,41	0,13	1,36	0,1352	0,6892
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	Neuropathy peripheral	136	10	7,35	126	92,65	NA	NA	NA	-	-	-	-	0,6892
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	Neuropathy peripheral	78	2	2,56	76	97,44	NA	NA	NA	0,65	0,10	4,22	0,6500	0,6892
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	Neuropathy peripheral	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,6892
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Nervous system disorders	Neuropathy peripheral	34	2	5,88	32	94,12	NA	NA	NA	1,65	0,20	13,70	0,6389	0,1657
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Nervous system disorders	Neuropathy peripheral	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,1657
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Nervous system disorders	Neuropathy peripheral	161	4	2,48	157	97,52	NA	NA	NA	0,30	0,10	0,95	0,0303	0,1657
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Nervous system disorders	Neuropathy peripheral	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	0,1657
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Neuropathy peripheral	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Neuropathy peripheral	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Neuropathy peripheral	171	6	3,51	165	96,49	NA	NA	NA	0,47	0,18	1,23	0,1137	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Neuropathy peripheral	185	13	7,03	172	92,97	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Nervous system disorders	Neuropathy peripheral	48	1	2,08	47	97,92	NA	NA	NA	0,24	0,03	2,18	0,1704	0,5220
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Nervous system disorders	Neuropathy peripheral	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,5220
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Nervous system disorders	Neuropathy peripheral	147	5	3,40	142	96,60	NA	NA	NA	0,54	0,18	1,62	0,2650	0,5220
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Nervous system disorders	Neuropathy peripheral	157	9	5,73	148	94,27	NA	NA	NA	-	-	-	-	0,5220
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	Neuropathy peripheral	98	3	3,06	95	96,94	NA	NA	NA	0,57	0,14	2,38	0,4324	0,6743
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	Neuropathy peripheral	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,6743
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	Neuropathy peripheral	97	3	3,09	94	96,91	NA	NA	NA	0,37	0,10	1,41	0,1304	0,6743
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	Neuropathy peripheral	100	8	8,00	92	92,00	NA	NA	NA	-	-	-	-	0,6743
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	Neuropathy peripheral	98	1	1,02	97	98,98	NA	NA	NA	0,13	0,02	1,02	0,0221	0,1272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	Neuropathy peripheral	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,1272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	Neuropathy peripheral	97	5	5,15	92	94,85	NA	NA	NA	0,84	0,24	2,89	0,7766	0,1272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	Neuropathy peripheral	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,1272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	Neuropathy peripheral	61	1	1,64	60	98,36	NA	NA	NA	0,21	0,02	1,78	0,1133	0,3862
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	Neuropathy peripheral	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,3862
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	Neuropathy peripheral	134	5	3,73	129	96,27	NA	NA	NA	0,61	0,20	1,86	0,3750	0,3862

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	Neuropathy peripheral	142	8	5,63	134	94,37	NA	NA	NA	-	-	-	-	0,3862
Patients with at least one AE	total	-	SVd Arm	Investigations	Weight decreased	195	51	26,15	144	73,85	NA	NA	NA	2,52	1,55	4,08	0,0001	NA
Patients with at least one AE	total	-	Vd Arm	Investigations	Weight decreased	204	25	12,25	179	87,75	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Blood and lymphatic system disorders	Neutropenia	80	15	18,75	65	81,25	NA	NA	NA	2,70	1,08	6,78	0,0281	0,8499
Patients with at least one AE	Gender	Female	Vd Arm	Blood and lymphatic system disorders	Neutropenia	91	7	7,69	84	92,31	NA	NA	NA	-	-	-	-	0,8499
Patients with at least one AE	Gender	Male	SVd Arm	Blood and lymphatic system disorders	Neutropenia	115	13	11,30	102	88,70	NA	NA	NA	3,11	1,01	9,62	0,0380	0,8499
Patients with at least one AE	Gender	Male	Vd Arm	Blood and lymphatic system disorders	Neutropenia	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,8499
Patients with at least one AE	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	Neutropenia	86	17	19,77	69	80,23	NA	NA	NA	15,98	2,11	120,99	0,0003	0,0261
Patients with at least one AE	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	Neutropenia	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,0261
Patients with at least one AE	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	Neutropenia	109	11	10,09	98	89,91	NA	NA	NA	1,32	0,55	3,12	0,5325	0,0261
Patients with at least one AE	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	Neutropenia	129	10	7,75	119	92,25	NA	NA	NA	-	-	-	-	0,0261
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Neutropenia	173	25	14,45	148	85,55	NA	NA	NA	2,85	1,33	6,14	0,0050	0,4575
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Neutropenia	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	0,4575
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Neutropenia	12	2	16,67	10	83,33	NA	NA	NA	1,23	0,15	9,87	0,8443	0,4575
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Neutropenia	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,4575
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Neutropenia	163	25	15,34	138	84,66	NA	NA	NA	3,02	1,41	6,47	0,0029	0,5189
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Neutropenia	173	9	5,20	164	94,80	NA	NA	NA	-	-	-	-	0,5189
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Neutropenia	32	3	9,38	29	90,62	NA	NA	NA	1,58	0,26	9,69	0,6192	0,5189
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Neutropenia	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,5189
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	Neutropenia	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,0564
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	Neutropenia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,0564
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	Neutropenia	61	9	14,75	52	85,25	NA	27,07	NA	2,42	0,73	8,06	0,1378	0,0564
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	Neutropenia	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,0564
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	Neutropenia	47	5	10,64	42	89,36	NA	NA	NA	0,93	0,27	3,25	0,9077	0,0564
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	Neutropenia	53	5	9,43	48	90,57	NA	NA	NA	-	-	-	-	0,0564

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	Neutropenia	69	13	18,84	56	81,16	NA	NA	NA	17,18	2,24	131,99	0,0002	0,0564
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	Neutropenia	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,0564
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	Neutropenia	117	16	13,68	101	86,32	NA	NA	NA	1,91	0,86	4,23	0,1042	0,0911
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	Neutropenia	136	10	7,35	126	92,65	NA	NA	NA	-	-	-	-	0,0911
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	Neutropenia	78	12	15,38	66	84,62	NA	NA	NA	12,68	1,64	98,06	0,0018	0,0911
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	Neutropenia	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,0911
Patients with at least one AE	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	Neutropenia	34	2	5,88	32	94,12	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	Neutropenia	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Blood and lymphatic system disorders	Neutropenia	161	26	16,15	135	83,85	NA	NA	NA	2,34	1,15	4,76	0,0153	NA
Patients with at least one AE	Race	White	Vd Arm	Blood and lymphatic system disorders	Neutropenia	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Neutropenia	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Neutropenia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Neutropenia	171	24	14,04	147	85,96	NA	NA	NA	2,37	1,16	4,85	0,0146	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Neutropenia	185	11	5,95	174	94,05	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	Neutropenia	48	3	6,25	45	93,75	NA	NA	NA	1,38	0,23	8,27	0,7245	0,4171
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	Neutropenia	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,4171
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	Neutropenia	147	25	17,01	122	82,99	NA	NA	NA	3,09	1,44	6,62	0,0023	0,4171
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	Neutropenia	157	9	5,73	148	94,27	NA	NA	NA	-	-	-	-	0,4171
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	Neutropenia	98	15	15,31	83	84,69	NA	NA	NA	2,29	0,93	5,63	0,0627	0,5409

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	Neutropenia	104	7	6,73	97	93,27	NA	NA	NA	-	-	-	-	0,5409
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	Neutropenia	97	13	13,40	84	86,60	NA	NA	NA	3,59	1,17	11,04	0,0171	0,5409
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	Neutropenia	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,5409
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	Neutropenia	98	9	9,18	89	90,82	NA	NA	NA	2,91	0,89	9,51	0,0651	0,9222
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	Neutropenia	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,9222
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	Neutropenia	97	19	19,59	78	80,41	NA	27,07	NA	2,70	1,13	6,45	0,0200	0,9222
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	Neutropenia	93	7	7,53	86	92,47	NA	NA	NA	-	-	-	-	0,9222
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	Neutropenia	61	5	8,20	56	91,80	NA	NA	NA	2,05	0,47	8,96	0,3305	0,5836
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	Neutropenia	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,5836
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	Neutropenia	134	23	17,16	111	82,84	NA	NA	NA	3,28	1,46	7,37	0,0023	0,5836
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	Neutropenia	142	8	5,63	134	94,37	NA	NA	NA	-	-	-	-	0,5836
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Blood and lymphatic system disorders	Neutropenia	195	17	8,72	178	91,28	NA	NA	NA	3,02	1,19	7,68	0,0145	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Blood and lymphatic system disorders	Neutropenia	204	6	2,94	198	97,06	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Blood and lymphatic system disorders	Neutropenia	80	9	11,25	71	88,75	NA	NA	NA	2,51	0,76	8,32	0,1197	0,7109
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Blood and lymphatic system disorders	Neutropenia	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,7109
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Blood and lymphatic system disorders	Neutropenia	115	8	6,96	107	93,04	NA	NA	NA	3,64	0,77	17,32	0,0824	0,7109
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Blood and lymphatic system disorders	Neutropenia	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,7109

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	Neutropenia	86	10	11,63	76	88,37	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	Neutropenia	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	Neutropenia	109	7	6,42	102	93,58	NA	NA	NA	1,36	0,45	4,07	0,5857	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	Neutropenia	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Neutropenia	173	15	8,67	158	91,33	NA	NA	NA	3,73	1,23	11,26	0,0124	0,2951
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Neutropenia	174	4	2,30	170	97,70	NA	NA	NA	-	-	-	-	0,2951
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Neutropenia	12	1	8,33	11	91,67	NA	NA	NA	0,91	0,08	10,04	0,9358	0,2951
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Neutropenia	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,2951
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Neutropenia	163	15	9,20	148	90,80	NA	NA	NA	3,91	1,30	11,78	0,0090	0,3476
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Neutropenia	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	0,3476
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Neutropenia	32	2	6,25	30	93,75	NA	NA	NA	1,33	0,19	9,49	0,7781	0,3476
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Neutropenia	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,3476
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	Neutropenia	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,2283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	Neutropenia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,2283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	Neutropenia	61	4	6,56	57	93,44	NA	NA	NA	1,35	0,30	6,10	0,6926	0,2283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	Neutropenia	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,2283

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	Neutropenia	47	3	6,38	44	93,62	NA	NA	NA	1,49	0,25	9,10	0,6608	0,2283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	Neutropenia	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,2283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	Neutropenia	69	9	13,04	60	86,96	NA	NA	NA	11,26	1,42	89,34	0,0040	0,2283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	Neutropenia	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,2283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	Neutropenia	117	9	7,69	108	92,31	NA	NA	NA	2,18	0,73	6,52	0,1538	0,2433
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	Neutropenia	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,2433
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	Neutropenia	78	8	10,26	70	89,74	NA	NA	NA	8,87	1,10	71,65	0,0139	0,2433
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	Neutropenia	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,2433
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	Neutropenia	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	Neutropenia	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Blood and lymphatic system disorders	Neutropenia	161	16	9,94	145	90,06	NA	NA	NA	2,57	1,00	6,60	0,0414	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Blood and lymphatic system disorders	Neutropenia	162	6	3,70	156	96,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Neutropenia	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Neutropenia	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Neutropenia	171	16	9,36	155	90,64	NA	NA	NA	2,90	1,13	7,43	0,0204	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Neutropenia	185	6	3,24	179	96,76	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	Neutropenia	48	2	4,17	46	95,83	NA	NA	NA	1,91	0,17	21,08	0,5914	0,6885
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	Neutropenia	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,6885
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	Neutropenia	147	15	10,20	132	89,80	NA	NA	NA	3,25	1,18	8,97	0,0158	0,6885
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	Neutropenia	157	5	3,18	152	96,82	NA	NA	NA	-	-	-	-	0,6885
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	Neutropenia	98	10	10,20	88	89,80	NA	NA	NA	2,75	0,86	8,78	0,0760	0,7931
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	Neutropenia	104	4	3,85	100	96,15	NA	NA	NA	-	-	-	-	0,7931
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	Neutropenia	97	7	7,22	90	92,78	NA	NA	NA	3,57	0,74	17,18	0,0903	0,7931
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	Neutropenia	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,7931
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	Neutropenia	98	6	6,12	92	93,88	NA	NA	NA	8,26	0,97	70,27	0,0225	0,2473
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	Neutropenia	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	0,2473
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	Neutropenia	97	11	11,34	86	88,66	NA	NA	NA	2,02	0,70	5,82	0,1845	0,2473
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	Neutropenia	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,2473
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	Neutropenia	61	3	4,92	58	95,08	NA	NA	NA	3,04	0,32	29,32	0,3117	0,9782
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	Neutropenia	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,9782
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	Neutropenia	134	14	10,45	120	89,55	NA	NA	NA	3,15	1,13	8,80	0,0212	0,9782

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	Neutropenia	142	5	3,52	137	96,48	NA	NA	NA	-	-	-	-	0,9782
Patients with at least one AE	total	-	SVd Arm	Investigations	-	195	88	45,13	107	54,87	9,92	6,24	NA	1,67	1,20	2,32	0,0022	NA
Patients with at least one AE	total	-	Vd Arm	Investigations	-	204	62	30,39	142	69,61	NA	21,65	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	General disorders and administration site conditions	Oedema peripheral	80	16	20,00	64	80,00	NA	NA	NA	1,64	0,71	3,75	0,2394	0,0067
Patients with at least one AE	Gender	Female	Vd Arm	General disorders and administration site conditions	Oedema peripheral	91	9	9,89	82	90,11	NA	NA	NA	-	-	-	-	0,0067
Patients with at least one AE	Gender	Male	SVd Arm	General disorders and administration site conditions	Oedema peripheral	115	7	6,09	108	93,91	NA	NA	NA	0,31	0,13	0,74	0,0057	0,0067
Patients with at least one AE	Gender	Male	Vd Arm	General disorders and administration site conditions	Oedema peripheral	113	20	17,70	93	82,30	NA	25,53	NA	-	-	-	-	0,0067
Patients with at least one AE	Age Group	<65	SVd Arm	General disorders and administration site conditions	Oedema peripheral	86	8	9,30	78	90,70	NA	NA	NA	0,77	0,29	2,05	0,6020	0,7902
Patients with at least one AE	Age Group	<65	Vd Arm	General disorders and administration site conditions	Oedema peripheral	75	9	12,00	66	88,00	NA	25,53	NA	-	-	-	-	0,7902
Patients with at least one AE	Age Group	>=65	SVd Arm	General disorders and administration site conditions	Oedema peripheral	109	15	13,76	94	86,24	NA	NA	NA	0,91	0,46	1,78	0,7765	0,7902
Patients with at least one AE	Age Group	>=65	Vd Arm	General disorders and administration site conditions	Oedema peripheral	129	20	15,50	109	84,50	NA	NA	NA	-	-	-	-	0,7902
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Oedema peripheral	173	21	12,14	152	87,86	NA	NA	NA	0,72	0,41	1,28	0,2632	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Oedema peripheral	174	28	16,09	146	83,91	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Oedema peripheral	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Oedema peripheral	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Oedema peripheral	163	20	12,27	143	87,73	NA	NA	NA	0,70	0,39	1,24	0,2177	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Oedema peripheral	173	29	16,76	144	83,24	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Oedema peripheral	32	3	9,38	29	90,62	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Oedema peripheral	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	General disorders and administration site conditions	Oedema peripheral	18	2	11,11	16	88,89	NA	NA	NA	0,50	0,04	5,54	0,5610	0,2923
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	General disorders and administration site conditions	Oedema peripheral	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,2923
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	General disorders and administration site conditions	Oedema peripheral	61	9	14,75	52	85,25	NA	NA	NA	0,49	0,22	1,10	0,0798	0,2923
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	General disorders and administration site conditions	Oedema peripheral	64	19	29,69	45	70,31	25,53	20,57	NA	-	-	-	-	0,2923
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	General disorders and administration site conditions	Oedema peripheral	47	3	6,38	44	93,62	-	-	-	-	-	-	-	0,2923
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	General disorders and administration site conditions	Oedema peripheral	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,2923
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	General disorders and administration site conditions	Oedema peripheral	69	9	13,04	60	86,96	NA	NA	NA	1,33	0,50	3,51	0,5649	0,2923
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	General disorders and administration site conditions	Oedema peripheral	70	8	11,43	62	88,57	NA	NA	NA	-	-	-	-	0,2923
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	General disorders and administration site conditions	Oedema peripheral	117	14	11,97	103	88,03	NA	NA	NA	0,75	0,37	1,50	0,4116	0,6890
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	General disorders and administration site conditions	Oedema peripheral	136	19	13,97	117	86,03	NA	NA	NA	-	-	-	-	0,6890
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	General disorders and administration site conditions	Oedema peripheral	78	9	11,54	69	88,46	NA	NA	NA	0,95	0,37	2,40	0,9106	0,6890
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	General disorders and administration site conditions	Oedema peripheral	68	10	14,71	58	85,29	NA	20,57	NA	-	-	-	-	0,6890
Patients with at least one AE	Race	Races other than White	SVd Arm	General disorders and administration site conditions	Oedema peripheral	34	6	17,65	28	82,35	NA	NA	NA	0,75	0,21	2,67	0,6565	0,8976
Patients with at least one AE	Race	Races other than White	Vd Arm	General disorders and administration site conditions	Oedema peripheral	42	10	23,81	32	76,19	20,57	17,74	NA	-	-	-	-	0,8976

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	SVd Arm	General disorders and administration site conditions	Oedema peripheral	161	17	10,56	144	89,44	NA	NA	NA	0,82	0,43	1,59	0,5660	0,8976
Patients with at least one AE	Race	White	Vd Arm	General disorders and administration site conditions	Oedema peripheral	162	19	11,73	143	88,27	NA	NA	NA	-	-	-	-	0,8976
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Oedema peripheral	6	1	16,67	5	83,33	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Oedema peripheral	5	1	20,00	4	80,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Oedema peripheral	171	20	11,70	151	88,30	NA	NA	NA	0,87	0,48	1,57	0,6371	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Oedema peripheral	185	25	13,51	160	86,49	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	General disorders and administration site conditions	Oedema peripheral	48	9	18,75	39	81,25	NA	NA	NA	1,46	0,52	4,13	0,4736	0,1955
Patients with at least one AE	Prior PI therapies	N	Vd Arm	General disorders and administration site conditions	Oedema peripheral	47	6	12,77	41	87,23	NA	NA	NA	-	-	-	-	0,1955
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	General disorders and administration site conditions	Oedema peripheral	147	14	9,52	133	90,48	NA	NA	NA	0,65	0,33	1,26	0,1946	0,1955
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	General disorders and administration site conditions	Oedema peripheral	157	23	14,65	134	85,35	NA	NA	NA	-	-	-	-	0,1955
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	General disorders and administration site conditions	Oedema peripheral	98	10	10,20	88	89,80	NA	NA	NA	0,58	0,27	1,27	0,1711	0,2164
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	General disorders and administration site conditions	Oedema peripheral	104	17	16,35	87	83,65	NA	25,53	NA	-	-	-	-	0,2164
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	General disorders and administration site conditions	Oedema peripheral	97	13	13,40	84	86,60	NA	NA	NA	1,17	0,53	2,58	0,6897	0,2164
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	General disorders and administration site conditions	Oedema peripheral	100	12	12,00	88	88,00	NA	NA	NA	-	-	-	-	0,2164
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	General disorders and administration site conditions	Oedema peripheral	98	12	12,24	86	87,76	NA	NA	NA	0,83	0,39	1,76	0,6281	0,9630

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	General disorders and administration site conditions	Oedema peripheral	111	17	15,32	94	84,68	NA	25,53	NA	-	-	-	-	0,9630
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	General disorders and administration site conditions	Oedema peripheral	97	11	11,34	86	88,66	NA	NA	NA	0,81	0,36	1,84	0,6120	0,9630
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	General disorders and administration site conditions	Oedema peripheral	93	12	12,90	81	87,10	NA	NA	NA	-	-	-	-	0,9630
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	General disorders and administration site conditions	Oedema peripheral	61	11	18,03	50	81,97	NA	NA	NA	1,16	0,49	2,76	0,7328	0,3589
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	General disorders and administration site conditions	Oedema peripheral	62	10	16,13	52	83,87	NA	NA	NA	-	-	-	-	0,3589
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	General disorders and administration site conditions	Oedema peripheral	134	12	8,96	122	91,04	NA	NA	NA	0,69	0,33	1,42	0,3049	0,3589
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	General disorders and administration site conditions	Oedema peripheral	142	19	13,38	123	86,62	NA	NA	NA	-	-	-	-	0,3589
Patients with at least one AE	total	-	SVd Arm	Metabolism and nutrition disorders	Decreased appetite	195	70	35,90	125	64,10	NA	NA	NA	8,66	4,46	16,83	0,0000	NA
Patients with at least one AE	total	-	Vd Arm	Metabolism and nutrition disorders	Decreased appetite	204	10	4,90	194	95,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	80	8	10,00	72	90,00	NA	NA	NA	3,76	0,69	20,51	0,1066	0,7928
Patients with at least one AE	Gender	Female	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,7928
Patients with at least one AE	Gender	Male	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	115	6	5,22	109	94,78	NA	NA	NA	2,75	0,55	13,76	0,2009	0,7928
Patients with at least one AE	Gender	Male	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,7928
Patients with at least one AE	Age Group	<65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	86	8	9,30	78	90,70	NA	NA	NA	5,96	0,73	48,87	0,0595	0,5788
Patients with at least one AE	Age Group	<65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,5788
Patients with at least one AE	Age Group	>=65	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	109	6	5,50	103	94,50	NA	NA	NA	2,91	0,72	11,80	0,1173	0,5788
Patients with at least one AE	Age Group	>=65	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	0,5788
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	173	13	7,51	160	92,49	NA	NA	NA	4,20	1,17	14,99	0,0170	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	163	13	7,98	150	92,02	NA	NA	NA	4,53	1,26	16,35	0,0121	0,3575
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	0,3575
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	32	1	3,12	31	96,88	NA	NA	NA	1,08	0,07	17,30	0,9566	0,3575
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,3575
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	18	4	22,22	14	77,78	-	-	-	-	-	-	-	0,5972
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,5972
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	61	5	8,20	56	91,80	NA	NA	NA	1,62	0,38	6,84	0,5094	0,5972
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,5972
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,5972
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,5972
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	69	4	5,80	65	94,20	NA	NA	NA	3,30	0,36	30,43	0,2652	0,5972
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,5972
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	117	9	7,69	108	92,31	NA	NA	NA	3,46	0,91	13,11	0,0531	0,9812
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	136	3	2,21	133	97,79	NA	NA	NA	-	-	-	-	0,9812
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	78	5	6,41	73	93,59	NA	NA	NA	3,57	0,41	31,38	0,2224	0,9812
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,9812
Patients with at least one AE	Race	Races other than White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	34	2	5,88	32	94,12	NA	NA	NA	1,22	0,17	8,95	0,8479	0,1921
Patients with at least one AE	Race	Races other than White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,1921
Patients with at least one AE	Race	White	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	161	12	7,45	149	92,55	NA	NA	NA	6,51	1,39	30,46	0,0073	0,1921
Patients with at least one AE	Race	White	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	0,1921
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	171	13	7,60	158	92,40	NA	NA	NA	3,56	1,13	11,24	0,0220	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	185	4	2,16	181	97,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	48	5	10,42	43	89,58	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	147	9	6,12	138	93,88	NA	NA	NA	2,40	0,73	7,87	0,1367	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	157	4	2,55	153	97,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	98	4	4,08	94	95,92	NA	NA	NA	4,78	0,52	43,76	0,1287	0,7584
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	0,7584
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	97	10	10,31	87	89,69	NA	NA	NA	3,19	0,86	11,83	0,0677	0,7584
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,7584
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	98	7	7,14	91	92,86	NA	NA	NA	6,22	0,75	51,81	0,0531	0,4226
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	0,4226
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	97	7	7,22	90	92,78	NA	NA	NA	2,21	0,56	8,77	0,2467	0,4226
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,4226
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	61	6	9,84	55	90,16	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	134	8	5,97	126	94,03	NA	NA	NA	2,12	0,63	7,17	0,2157	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Metabolism and nutrition disorders	Hyperglycaemia	195	14	7,18	181	92,82	NA	NA	NA	1,42	0,64	3,14	0,3834	NA
Patients with at least one AE	total	-	Vd Arm	Metabolism and nutrition disorders	Hyperglycaemia	204	11	5,39	193	94,61	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Injury, poisoning and procedural complications	Overdose	80	5	6,25	75	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Female	Vd Arm	Injury, poisoning and procedural complications	Overdose	91	0	0,00	91	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Male	SVd Arm	Injury, poisoning and procedural complications	Overdose	115	5	4,35	110	95,65	-	-	-	-	-	-	-	NA
Patients with at least one AE	Gender	Male	Vd Arm	Injury, poisoning and procedural complications	Overdose	113	0	0,00	113	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Age Group	<65	SVd Arm	Injury, poisoning and procedural complications	Overdose	86	0	0,00	86	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Age Group	<65	Vd Arm	Injury, poisoning and procedural complications	Overdose	75	0	0,00	75	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Age Group	>=65	SVd Arm	Injury, poisoning and procedural complications	Overdose	109	10	9,17	99	90,83	-	-	-	-	-	-	-	NA
Patients with at least one AE	Age Group	>=65	Vd Arm	Injury, poisoning and procedural complications	Overdose	129	0	0,00	129	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	Overdose	173	9	5,20	164	94,80	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	Overdose	174	0	0,00	174	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	Overdose	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	Overdose	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	Overdose	163	8	4,91	155	95,09	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	Overdose	173	0	0,00	173	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	Overdose	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	Overdose	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Injury, poisoning and procedural complications	Overdose	18	2	11,11	16	88,89	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Injury, poisoning and procedural complications	Overdose	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Injury, poisoning and procedural complications	Overdose	61	6	9,84	55	90,16	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Injury, poisoning and procedural complications	Overdose	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Injury, poisoning and procedural complications	Overdose	47	0	0,00	47	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Injury, poisoning and procedural complications	Overdose	53	0	0,00	53	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Injury, poisoning and procedural complications	Overdose	69	2	2,90	67	97,10	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Injury, poisoning and procedural complications	Overdose	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Injury, poisoning and procedural complications	Overdose	117	6	5,13	111	94,87	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Injury, poisoning and procedural complications	Overdose	136	0	0,00	136	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Injury, poisoning and procedural complications	Overdose	78	4	5,13	74	94,87	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Injury, poisoning and procedural complications	Overdose	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	SVd Arm	Injury, poisoning and procedural complications	Overdose	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Injury, poisoning and procedural complications	Overdose	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	SVd Arm	Injury, poisoning and procedural complications	Overdose	161	9	5,59	152	94,41	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	Vd Arm	Injury, poisoning and procedural complications	Overdose	162	0	0,00	162	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	Overdose	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	Overdose	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	Overdose	171	8	4,68	163	95,32	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	Overdose	185	0	0,00	185	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Injury, poisoning and procedural complications	Overdose	48	4	8,33	44	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Injury, poisoning and procedural complications	Overdose	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Injury, poisoning and procedural complications	Overdose	147	6	4,08	141	95,92	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Injury, poisoning and procedural complications	Overdose	157	0	0,00	157	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Injury, poisoning and procedural complications	Overdose	98	6	6,12	92	93,88	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Injury, poisoning and procedural complications	Overdose	104	0	0,00	104	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Injury, poisoning and procedural complications	Overdose	97	4	4,12	93	95,88	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Injury, poisoning and procedural complications	Overdose	100	0	0,00	100	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Injury, poisoning and procedural complications	Overdose	98	3	3,06	95	96,94	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Injury, poisoning and procedural complications	Overdose	111	0	0,00	111	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Injury, poisoning and procedural complications	Overdose	97	7	7,22	90	92,78	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Injury, poisoning and procedural complications	Overdose	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Injury, poisoning and procedural complications	Overdose	61	5	8,20	56	91,80	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Injury, poisoning and procedural complications	Overdose	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Injury, poisoning and procedural complications	Overdose	134	5	3,73	129	96,27	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Injury, poisoning and procedural complications	Overdose	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Metabolism and nutrition disorders	Hypocalcaemia	195	15	7,69	180	92,31	NA	NA	NA	2,63	1,01	6,84	0,0400	NA
Patients with at least one AE	total	-	Vd Arm	Metabolism and nutrition disorders	Hypocalcaemia	204	6	2,94	198	97,06	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	80	6	7,50	74	92,50	NA	NA	NA	0,86	0,29	2,56	0,7800	0,4462
Patients with at least one AE	Gender	Female	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	91	8	8,79	83	91,21	NA	NA	NA	-	-	-	-	0,4462
Patients with at least one AE	Gender	Male	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	115	4	3,48	111	96,52	NA	NA	NA	0,46	0,14	1,49	0,1842	0,4462
Patients with at least one AE	Gender	Male	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	0,4462
Patients with at least one AE	Age Group	<65	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	86	7	8,14	79	91,86	NA	NA	NA	0,69	0,23	2,03	0,4976	0,6175
Patients with at least one AE	Age Group	<65	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,6175
Patients with at least one AE	Age Group	>=65	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	109	3	2,75	106	97,25	NA	NA	NA	0,45	0,12	1,66	0,2161	0,6175
Patients with at least one AE	Age Group	>=65	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	129	9	6,98	120	93,02	NA	NA	NA	-	-	-	-	0,6175

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	173	7	4,05	166	95,95	NA	NA	NA	0,46	0,19	1,14	0,0875	0,3552
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	174	15	8,62	159	91,38	NA	NA	NA	-	-	-	-	0,3552
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	12	3	25,00	9	75,00	16,30	NA	NA	1,66	0,13	21,23	0,6944	0,3552
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,3552
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	163	7	4,29	156	95,71	NA	NA	NA	0,51	0,21	1,26	0,1382	0,3651
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	173	14	8,09	159	91,91	NA	NA	NA	-	-	-	-	0,3651
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	32	3	9,38	29	90,62	NA	16,30	NA	1,22	0,23	6,46	0,8124	0,3651
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,3651
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,2949
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	17	2	11,76	15	88,24	-	-	-	-	-	-	-	0,2949
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	61	4	6,56	57	93,44	NA	NA	NA	0,48	0,14	1,57	0,2118	0,2949
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	64	9	14,06	55	85,94	NA	NA	NA	-	-	-	-	0,2949
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	47	1	2,13	46	97,87	NA	NA	NA	0,32	0,03	2,91	0,2854	0,2949
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,2949
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	69	4	5,80	65	94,20	NA	NA	NA	2,07	0,38	11,30	0,3921	0,2949
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,2949

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	117	6	5,13	111	94,87	NA	NA	NA	0,44	0,17	1,16	0,0877	0,1985
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	136	15	11,03	121	88,97	NA	NA	NA	-	-	-	-	0,1985
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	78	4	5,13	74	94,87	NA	NA	NA	1,60	0,29	8,83	0,5856	0,1985
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,1985
Patients with at least one AE	Race	Races other than White	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	34	4	11,76	30	88,24	NA	NA	NA	1,43	0,31	6,54	0,6424	0,2193
Patients with at least one AE	Race	Races other than White	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	42	4	9,52	38	90,48	NA	NA	NA	-	-	-	-	0,2193
Patients with at least one AE	Race	White	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	161	6	3,73	155	96,27	NA	NA	NA	0,46	0,17	1,23	0,1124	0,2193
Patients with at least one AE	Race	White	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	162	13	8,02	149	91,98	NA	NA	NA	-	-	-	-	0,2193
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	171	8	4,68	163	95,32	NA	NA	NA	0,58	0,25	1,38	0,2122	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	185	15	8,11	170	91,89	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	48	1	2,08	47	97,92	NA	NA	NA	0,32	0,03	3,08	0,2990	0,5281
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,5281
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	147	9	6,12	138	93,88	NA	NA	NA	0,70	0,30	1,62	0,4001	0,5281

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	157	14	8,92	143	91,08	NA	NA	NA	-	-	-	-	0,5281
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	98	3	3,06	95	96,94	NA	NA	NA	0,40	0,10	1,50	0,1586	0,3809
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	104	8	7,69	96	92,31	NA	NA	NA	-	-	-	-	0,3809
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	97	7	7,22	90	92,78	NA	NA	NA	0,83	0,31	2,25	0,7175	0,3809
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	100	9	9,00	91	91,00	NA	NA	NA	-	-	-	-	0,3809
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	98	5	5,10	93	94,90	NA	NA	NA	0,73	0,24	2,20	0,5775	0,6952
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	111	9	8,11	102	91,89	NA	NA	NA	-	-	-	-	0,6952
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	97	5	5,15	92	94,85	NA	NA	NA	0,53	0,17	1,65	0,2681	0,6952
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	93	8	8,60	85	91,40	NA	NA	NA	-	-	-	-	0,6952
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	61	2	3,28	59	96,72	NA	NA	NA	0,37	0,07	1,99	0,2293	0,4721
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,4721
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	134	8	5,97	126	94,03	NA	NA	NA	0,74	0,30	1,83	0,5169	0,4721
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	142	12	8,45	130	91,55	NA	NA	NA	-	-	-	-	0,4721
Patients with at least one AE	total	-	SVd Arm	Metabolism and nutrition disorders	Hypokalaemia	195	18	9,23	177	90,77	NA	NA	NA	1,72	0,80	3,67	0,1572	NA
Patients with at least one AE	total	-	Vd Arm	Metabolism and nutrition disorders	Hypokalaemia	204	11	5,39	193	94,61	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Nervous system disorders	Paraesthesia	80	3	3,75	77	96,25	NA	NA	NA	0,46	0,12	1,81	0,2556	0,6329
Patients with at least one AE	Gender	Female	Vd Arm	Nervous system disorders	Paraesthesia	91	8	8,79	83	91,21	NA	NA	NA	-	-	-	-	0,6329
Patients with at least one AE	Gender	Male	SVd Arm	Nervous system disorders	Paraesthesia	115	2	1,74	113	98,26	NA	NA	NA	0,28	0,06	1,32	0,0855	0,6329

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Male	Vd Arm	Nervous system disorders	Paraesthesia	113	8	7,08	105	92,92	NA	NA	NA	-	-	-	-	0,6329
Patients with at least one AE	Age Group	<65	SVd Arm	Nervous system disorders	Paraesthesia	86	5	5,81	81	94,19	NA	NA	NA	0,51	0,16	1,59	0,2380	NA
Patients with at least one AE	Age Group	<65	Vd Arm	Nervous system disorders	Paraesthesia	75	9	12,00	66	88,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Age Group	>=65	SVd Arm	Nervous system disorders	Paraesthesia	109	0	0,00	109	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Age Group	>=65	Vd Arm	Nervous system disorders	Paraesthesia	129	7	5,43	122	94,57	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Paraesthesia	173	3	1,73	170	98,27	NA	NA	NA	0,21	0,06	0,74	0,0078	0,1772
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Paraesthesia	174	14	8,05	160	91,95	NA	NA	NA	-	-	-	-	0,1772
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	Paraesthesia	12	2	16,67	10	83,33	NA	NA	NA	1,51	0,12	19,77	0,7532	0,1772
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	Paraesthesia	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,1772
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Paraesthesia	163	3	1,84	160	98,16	NA	NA	NA	0,21	0,06	0,73	0,0066	0,1339
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Paraesthesia	173	14	8,09	159	91,91	NA	NA	NA	-	-	-	-	0,1339
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	Paraesthesia	32	2	6,25	30	93,75	NA	NA	NA	1,30	0,17	10,04	0,8019	0,1339
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	Paraesthesia	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,1339
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	Paraesthesia	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	Paraesthesia	17	1	5,88	16	94,12	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	Paraesthesia	61	0	0,00	61	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	Paraesthesia	64	7	10,94	57	89,06	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	Paraesthesia	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	Paraesthesia	53	1	1,89	52	98,11	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	Paraesthesia	69	4	5,80	65	94,20	NA	NA	NA	0,58	0,17	1,98	0,3780	NA
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	Paraesthesia	70	7	10,00	63	90,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	Paraesthesia	117	1	0,85	116	99,15	NA	NA	NA	0,12	0,01	0,99	0,0218	0,2728
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	Paraesthesia	136	9	6,62	127	93,38	NA	NA	NA	-	-	-	-	0,2728

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	Paraesthesia	78	4	5,13	74	94,87	NA	NA	NA	0,47	0,14	1,63	0,2243	0,2728
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	Paraesthesia	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,2728
Patients with at least one AE	Race	Races other than White	SVd Arm	Nervous system disorders	Paraesthesia	34	4	11,76	30	88,24	NA	NA	NA	0,61	0,18	2,03	0,4155	0,3083
Patients with at least one AE	Race	Races other than White	Vd Arm	Nervous system disorders	Paraesthesia	42	9	21,43	33	78,57	NA	NA	NA	-	-	-	-	0,3083
Patients with at least one AE	Race	White	SVd Arm	Nervous system disorders	Paraesthesia	161	1	0,62	160	99,38	NA	NA	NA	0,17	0,02	1,43	0,0664	0,3083
Patients with at least one AE	Race	White	Vd Arm	Nervous system disorders	Paraesthesia	162	7	4,32	155	95,68	NA	NA	NA	-	-	-	-	0,3083
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Paraesthesia	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Paraesthesia	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Paraesthesia	171	4	2,34	167	97,66	NA	NA	NA	0,32	0,10	0,99	0,0375	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Paraesthesia	185	14	7,57	171	92,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Nervous system disorders	Paraesthesia	48	0	0,00	48	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Nervous system disorders	Paraesthesia	47	4	8,51	43	91,49	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Nervous system disorders	Paraesthesia	147	5	3,40	142	96,60	NA	NA	NA	0,45	0,16	1,29	0,1268	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Nervous system disorders	Paraesthesia	157	12	7,64	145	92,36	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	Paraesthesia	98	1	1,02	97	98,98	NA	NA	NA	0,14	0,02	1,14	0,0318	0,3065
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	Paraesthesia	104	7	6,73	97	93,27	NA	NA	NA	-	-	-	-	0,3065
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	Paraesthesia	97	4	4,12	93	95,88	NA	NA	NA	0,49	0,15	1,63	0,2371	0,3065
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	Paraesthesia	100	9	9,00	91	91,00	NA	NA	NA	-	-	-	-	0,3065
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	Paraesthesia	98	4	4,08	94	95,92	NA	NA	NA	0,33	0,11	1,03	0,0468	0,8725

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	Paraesthesia	111	14	12,61	97	87,39	NA	NA	NA	-	-	-	-	0,8725
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	Paraesthesia	97	1	1,03	96	98,97	NA	NA	NA	0,41	0,04	4,54	0,4535	0,8725
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	Paraesthesia	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,8725
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	Paraesthesia	61	0	0,00	61	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	Paraesthesia	62	5	8,06	57	91,94	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	Paraesthesia	134	5	3,73	129	96,27	NA	NA	NA	0,46	0,16	1,34	0,1462	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	Paraesthesia	142	11	7,75	131	92,25	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Metabolism and nutrition disorders	Hyponatraemia	195	13	6,67	182	93,33	NA	NA	NA	4,71	1,34	16,57	0,0078	NA
Patients with at least one AE	total	-	Vd Arm	Metabolism and nutrition disorders	Hyponatraemia	204	3	1,47	201	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	80	8	10,00	72	90,00	NA	NA	NA	0,71	0,29	1,77	0,4601	0,8886
Patients with at least one AE	Gender	Female	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	91	12	13,19	79	86,81	NA	NA	NA	-	-	-	-	0,8886
Patients with at least one AE	Gender	Male	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	115	11	9,57	104	90,43	NA	NA	NA	0,77	0,35	1,71	0,5251	0,8886
Patients with at least one AE	Gender	Male	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	113	14	12,39	99	87,61	NA	NA	NA	-	-	-	-	0,8886
Patients with at least one AE	Age Group	<65	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	86	11	12,79	75	87,21	NA	NA	NA	1,02	0,41	2,57	0,9655	0,3172
Patients with at least one AE	Age Group	<65	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,3172
Patients with at least one AE	Age Group	>=65	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	109	8	7,34	101	92,66	NA	NA	NA	0,54	0,23	1,25	0,1443	0,3172
Patients with at least one AE	Age Group	>=65	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	129	18	13,95	111	86,05	NA	NA	NA	-	-	-	-	0,3172
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	173	17	9,83	156	90,17	NA	NA	NA	0,78	0,41	1,47	0,4363	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	174	22	12,64	152	87,36	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	163	17	10,43	146	89,57	NA	NA	NA	0,75	0,40	1,41	0,3720	0,9526
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	173	24	13,87	149	86,13	NA	NA	NA	-	-	-	-	0,9526
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	32	2	6,25	30	93,75	NA	NA	NA	0,71	0,10	5,17	0,7316	0,9526
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,9526
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,9037
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	17	2	11,76	15	88,24	-	-	-	-	-	-	-	0,9037
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	61	5	8,20	56	91,80	NA	NA	NA	0,94	0,28	3,10	0,9173	0,9037
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,9037
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	47	8	17,02	39	82,98	NA	NA	NA	0,94	0,36	2,45	0,8974	0,9037
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	53	9	16,98	44	83,02	NA	NA	NA	-	-	-	-	0,9037
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	69	6	8,70	63	91,30	NA	NA	NA	0,70	0,24	2,01	0,5017	0,9037
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	70	9	12,86	61	87,14	NA	NA	NA	-	-	-	-	0,9037
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	117	13	11,11	104	88,89	NA	NA	NA	1,00	0,47	2,12	0,9977	0,2844
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	136	15	11,03	121	88,97	NA	NA	NA	-	-	-	-	0,2844
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	78	6	7,69	72	92,31	NA	NA	NA	0,50	0,18	1,39	0,1766	0,2844
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	68	11	16,18	57	83,82	NA	NA	NA	-	-	-	-	0,2844
Patients with at least one AE	Race	Races other than White	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	34	3	8,82	31	91,18	NA	NA	NA	0,77	0,16	3,78	0,7432	0,9225
Patients with at least one AE	Race	Races other than White	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	42	4	9,52	38	90,48	NA	NA	NA	-	-	-	-	0,9225
Patients with at least one AE	Race	White	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	161	16	9,94	145	90,06	NA	NA	NA	0,70	0,37	1,35	0,2862	0,9225
Patients with at least one AE	Race	White	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	162	22	13,58	140	86,42	NA	NA	NA	-	-	-	-	0,9225
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	171	18	10,53	153	89,47	NA	NA	NA	0,79	0,43	1,45	0,4372	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	185	25	13,51	160	86,49	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	48	2	4,17	46	95,83	NA	NA	NA	0,16	0,04	0,72	0,0060	0,0136
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	47	11	23,40	36	76,60	NA	NA	NA	-	-	-	-	0,0136
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	147	17	11,56	130	88,44	NA	NA	NA	1,28	0,64	2,58	0,4815	0,0136
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	157	15	9,55	142	90,45	NA	NA	NA	-	-	-	-	0,0136
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	98	8	8,16	90	91,84	NA	NA	NA	0,61	0,25	1,48	0,2735	0,4999
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	104	13	12,50	91	87,50	NA	NA	NA	-	-	-	-	0,4999
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	97	11	11,34	86	88,66	NA	NA	NA	0,93	0,41	2,08	0,8522	0,4999
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	100	13	13,00	87	87,00	NA	NA	NA	-	-	-	-	0,4999
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	98	7	7,14	91	92,86	NA	NA	NA	0,51	0,21	1,26	0,1372	0,1950
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	111	16	14,41	95	85,59	NA	NA	NA	-	-	-	-	0,1950
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	97	12	12,37	85	87,63	NA	NA	NA	1,16	0,50	2,71	0,7337	0,1950
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	93	10	10,75	83	89,25	NA	NA	NA	-	-	-	-	0,1950
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	61	6	9,84	55	90,16	NA	NA	NA	0,32	0,10	1,00	0,0397	0,0942
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	62	12	19,35	50	80,65	NA	NA	NA	-	-	-	-	0,0942
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	134	13	9,70	121	90,30	NA	NA	NA	1,03	0,48	2,21	0,9311	0,0942

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	142	14	9,86	128	90,14	NA	NA	NA	-	-	-	-	0,0942
Patients with at least one AE	total	-	SVd Arm	Metabolism and nutrition disorders	Hypophosphataemia	195	16	8,21	179	91,79	NA	NA	NA	2,25	0,92	5,51	0,0693	NA
Patients with at least one AE	total	-	Vd Arm	Metabolism and nutrition disorders	Hypophosphataemia	204	7	3,43	197	96,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Infections and infestations	Pneumonia	80	13	16,25	67	83,75	NA	34,50	NA	1,46	0,65	3,28	0,3519	0,5086
Patients with at least one AE	Gender	Female	Vd Arm	Infections and infestations	Pneumonia	91	13	14,29	78	85,71	NA	NA	NA	-	-	-	-	0,5086
Patients with at least one AE	Gender	Male	SVd Arm	Infections and infestations	Pneumonia	115	20	17,39	95	82,61	NA	NA	NA	1,04	0,55	1,95	0,9120	0,5086
Patients with at least one AE	Gender	Male	Vd Arm	Infections and infestations	Pneumonia	113	19	16,81	94	83,19	NA	NA	NA	-	-	-	-	0,5086
Patients with at least one AE	Age Group	<65	SVd Arm	Infections and infestations	Pneumonia	86	18	20,93	68	79,07	NA	34,50	NA	1,40	0,66	2,97	0,3789	0,3816
Patients with at least one AE	Age Group	<65	Vd Arm	Infections and infestations	Pneumonia	75	12	16,00	63	84,00	NA	NA	NA	-	-	-	-	0,3816
Patients with at least one AE	Age Group	>=65	SVd Arm	Infections and infestations	Pneumonia	109	15	13,76	94	86,24	NA	NA	NA	0,89	0,45	1,75	0,7381	0,3816
Patients with at least one AE	Age Group	>=65	Vd Arm	Infections and infestations	Pneumonia	129	20	15,50	109	84,50	NA	NA	NA	-	-	-	-	0,3816
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Pneumonia	173	28	16,18	145	83,82	NA	NA	NA	0,99	0,58	1,68	0,9560	0,1892
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Pneumonia	174	28	16,09	146	83,91	NA	NA	NA	-	-	-	-	0,1892
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Pneumonia	12	5	41,67	7	58,33	NA	3,06	NA	3,27	0,59	18,04	0,1558	0,1892
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Pneumonia	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,1892
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Pneumonia	163	20	12,27	143	87,73	NA	NA	NA	0,75	0,42	1,35	0,3404	0,0156
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Pneumonia	173	27	15,61	146	84,39	NA	NA	NA	-	-	-	-	0,0156
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Pneumonia	32	13	40,62	19	59,38	12,55	6,80	NA	3,37	1,16	9,76	0,0186	0,0156
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Pneumonia	31	5	16,13	26	83,87	NA	20,90	NA	-	-	-	-	0,0156
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Pneumonia	18	2	11,11	16	88,89	NA	NA	NA	0,45	0,04	5,02	0,5079	0,8982
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Pneumonia	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,8982
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Pneumonia	61	9	14,75	52	85,25	34,50	17,68	NA	1,09	0,39	3,07	0,8674	0,8982
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Pneumonia	64	7	10,94	57	89,06	NA	NA	NA	-	-	-	-	0,8982
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Pneumonia	47	7	14,89	40	85,11	NA	NA	NA	0,83	0,28	2,47	0,7405	0,8982

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Pneumonia	53	8	15,09	45	84,91	NA	NA	NA	-	-	-	-	0,8982
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Pneumonia	69	15	21,74	54	78,26	NA	NA	NA	1,08	0,53	2,21	0,8366	0,8982
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Pneumonia	70	15	21,43	55	78,57	NA	NA	NA	-	-	-	-	0,8982
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Pneumonia	117	15	12,82	102	87,18	NA	NA	NA	0,94	0,46	1,90	0,8562	0,7811
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Pneumonia	136	17	12,50	119	87,50	NA	NA	NA	-	-	-	-	0,7811
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Pneumonia	78	18	23,08	60	76,92	NA	NA	NA	1,08	0,54	2,15	0,8319	0,7811
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Pneumonia	68	15	22,06	53	77,94	NA	NA	NA	-	-	-	-	0,7811
Patients with at least one AE	Race	Races other than White	SVd Arm	Infections and infestations	Pneumonia	34	5	14,71	29	85,29	NA	NA	NA	1,21	0,33	4,45	0,7692	0,8400
Patients with at least one AE	Race	Races other than White	Vd Arm	Infections and infestations	Pneumonia	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,8400
Patients with at least one AE	Race	White	SVd Arm	Infections and infestations	Pneumonia	161	28	17,39	133	82,61	NA	NA	NA	1,05	0,61	1,80	0,8576	0,8400
Patients with at least one AE	Race	White	Vd Arm	Infections and infestations	Pneumonia	162	27	16,67	135	83,33	NA	NA	NA	-	-	-	-	0,8400
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Pneumonia	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Pneumonia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Pneumonia	171	28	16,37	143	83,63	NA	NA	NA	1,01	0,60	1,71	0,9581	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Pneumonia	185	30	16,22	155	83,78	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Infections and infestations	Pneumonia	48	6	12,50	42	87,50	NA	NA	NA	0,69	0,24	2,00	0,4902	0,3323
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Infections and infestations	Pneumonia	47	8	17,02	39	82,98	NA	NA	NA	-	-	-	-	0,3323
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Infections and infestations	Pneumonia	147	27	18,37	120	81,63	NA	34,50	NA	1,25	0,72	2,17	0,4331	0,3323
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Infections and infestations	Pneumonia	157	24	15,29	133	84,71	NA	NA	NA	-	-	-	-	0,3323

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Pneumonia	98	18	18,37	80	81,63	NA	34,50	NA	1,18	0,60	2,30	0,6310	0,7627
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Pneumonia	104	17	16,35	87	83,65	NA	NA	NA	-	-	-	-	0,7627
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Pneumonia	97	15	15,46	82	84,54	NA	NA	NA	1,01	0,49	2,09	0,9742	0,7627
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Pneumonia	100	15	15,00	85	85,00	NA	NA	NA	-	-	-	-	0,7627
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Pneumonia	98	13	13,27	85	86,73	NA	NA	NA	0,84	0,41	1,73	0,6416	0,3470
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Pneumonia	111	18	16,22	93	83,78	NA	NA	NA	-	-	-	-	0,3470
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Pneumonia	97	20	20,62	77	79,38	NA	NA	NA	1,37	0,68	2,77	0,3831	0,3470
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Pneumonia	93	14	15,05	79	84,95	NA	NA	NA	-	-	-	-	0,3470
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Pneumonia	61	8	13,11	53	86,89	NA	34,50	NA	0,69	0,24	2,00	0,4902	0,3976
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Pneumonia	62	8	12,90	54	87,10	NA	NA	NA	-	-	-	-	0,3976
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Pneumonia	134	25	18,66	109	81,34	NA	NA	NA	1,16	0,66	2,04	0,6086	0,3976
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Pneumonia	142	24	16,90	118	83,10	NA	NA	NA	-	-	-	-	0,3976
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Infections and infestations	Pneumonia	195	23	11,79	172	88,21	NA	NA	NA	1,06	0,59	1,90	0,8497	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Infections and infestations	Pneumonia	204	23	11,27	181	88,73	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Infections and infestations	Pneumonia	80	12	15,00	68	85,00	NA	34,50	NA	1,85	0,76	4,49	0,1695	0,1830
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Infections and infestations	Pneumonia	91	10	10,99	81	89,01	NA	NA	NA	-	-	-	-	0,1830
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Infections and infestations	Pneumonia	115	11	9,57	104	90,43	NA	NA	NA	0,82	0,37	1,83	0,6255	0,1830

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Infections and infestations	Pneumonia	113	13	11,50	100	88,50	NA	NA	NA	-	-	-	-	0,1830
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Infections and infestations	Pneumonia	86	12	13,95	74	86,05	NA	NA	NA	1,99	0,73	5,43	0,1704	0,1432
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Infections and infestations	Pneumonia	75	6	8,00	69	92,00	NA	NA	NA	-	-	-	-	0,1432
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Infections and infestations	Pneumonia	109	11	10,09	98	89,91	NA	NA	NA	0,78	0,36	1,67	0,5164	0,1432
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Infections and infestations	Pneumonia	129	17	13,18	112	86,82	NA	NA	NA	-	-	-	-	0,1432
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Pneumonia	173	21	12,14	152	87,86	NA	NA	NA	1,05	0,56	1,95	0,8797	0,6624
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Pneumonia	174	20	11,49	154	88,51	NA	NA	NA	-	-	-	-	0,6624
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Pneumonia	12	2	16,67	10	83,33	NA	NA	NA	1,86	0,15	22,60	0,6214	0,6624
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Pneumonia	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,6624
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Pneumonia	163	13	7,98	150	92,02	NA	NA	NA	0,67	0,33	1,35	0,2575	0,0154
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Pneumonia	173	20	11,56	153	88,44	NA	NA	NA	-	-	-	-	0,0154
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Pneumonia	32	10	31,25	22	68,75	NA	7,00	NA	4,25	1,13	15,96	0,0211	0,0154
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Pneumonia	31	3	9,68	28	90,32	NA	20,90	NA	-	-	-	-	0,0154
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Pneumonia	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,7732
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Pneumonia	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,7732
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Pneumonia	61	5	8,20	56	91,80	NA	34,50	NA	1,12	0,25	5,07	0,8847	0,7732

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Pneumonia	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,7732
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Pneumonia	47	7	14,89	40	85,11	NA	NA	NA	1,27	0,39	4,16	0,6884	0,7732
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Pneumonia	53	6	11,32	47	88,68	NA	NA	NA	-	-	-	-	0,7732
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Pneumonia	69	10	14,49	59	85,51	NA	NA	NA	0,77	0,34	1,77	0,5433	0,7732
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Pneumonia	70	13	18,57	57	81,43	NA	NA	NA	-	-	-	-	0,7732
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Pneumonia	117	11	9,40	106	90,60	NA	NA	NA	1,06	0,45	2,50	0,8875	0,7067
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Pneumonia	136	11	8,09	125	91,91	NA	NA	NA	-	-	-	-	0,7067
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Pneumonia	78	12	15,38	66	84,62	NA	NA	NA	0,85	0,38	1,90	0,6900	0,7067
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Pneumonia	68	12	17,65	56	82,35	NA	NA	NA	-	-	-	-	0,7067
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Infections and infestations	Pneumonia	34	3	8,82	31	91,18	NA	NA	NA	1,14	0,21	6,09	0,8760	0,8613
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Infections and infestations	Pneumonia	42	3	7,14	39	92,86	NA	NA	NA	-	-	-	-	0,8613
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Infections and infestations	Pneumonia	161	20	12,42	141	87,58	NA	NA	NA	0,97	0,52	1,84	0,9351	0,8613
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Infections and infestations	Pneumonia	162	20	12,35	142	87,65	NA	NA	NA	-	-	-	-	0,8613
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Pneumonia	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Pneumonia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Pneumonia	171	20	11,70	151	88,30	NA	NA	NA	0,98	0,53	1,80	0,9406	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Pneumonia	185	22	11,89	163	88,11	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Infections and infestations	Pneumonia	48	5	10,42	43	89,58	NA	NA	NA	1,18	0,31	4,50	0,8051	0,8555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Infections and infestations	Pneumonia	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,8555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Infections and infestations	Pneumonia	147	18	12,24	129	87,76	NA	NA	NA	1,03	0,54	1,98	0,9283	0,8555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Infections and infestations	Pneumonia	157	19	12,10	138	87,90	NA	NA	NA	-	-	-	-	0,8555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Pneumonia	98	14	14,29	84	85,71	NA	34,50	NA	1,31	0,60	2,86	0,4944	0,4133
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Pneumonia	104	12	11,54	92	88,46	NA	NA	NA	-	-	-	-	0,4133
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Pneumonia	97	9	9,28	88	90,72	NA	NA	NA	0,80	0,33	1,95	0,6227	0,4133
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Pneumonia	100	11	11,00	89	89,00	NA	NA	NA	-	-	-	-	0,4133
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Pneumonia	98	9	9,18	89	90,82	NA	NA	NA	0,89	0,37	2,12	0,7934	0,5994
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Pneumonia	111	12	10,81	99	89,19	NA	NA	NA	-	-	-	-	0,5994
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Pneumonia	97	14	14,43	83	85,57	NA	NA	NA	1,23	0,54	2,79	0,6251	0,5994
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Pneumonia	93	11	11,83	82	88,17	NA	NA	NA	-	-	-	-	0,5994
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Pneumonia	61	7	11,48	54	88,52	NA	34,50	NA	1,18	0,31	4,50	0,8051	0,7245
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Pneumonia	62	4	6,45	58	93,55	NA	NA	NA	-	-	-	-	0,7245
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Pneumonia	134	16	11,94	118	88,06	NA	NA	NA	0,90	0,46	1,77	0,7685	0,7245

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Pneumonia	142	19	13,38	123	86,62	NA	NA	NA	-	-	-	-	0,7245
Patients with at least one SAE	total	-	SVd Arm	Infections and infestations	Pneumonia	195	24	12,31	171	87,69	NA	NA	NA	1,02	0,58	1,80	0,9369	NA
Patients with at least one SAE	total	-	Vd Arm	Infections and infestations	Pneumonia	204	25	12,25	179	87,75	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	Infections and infestations	Pneumonia	80	10	12,50	70	87,50	NA	34,50	NA	1,24	0,51	2,98	0,6382	0,8057
Patients with at least one SAE	Gender	Female	Vd Arm	Infections and infestations	Pneumonia	91	12	13,19	79	86,81	NA	NA	NA	-	-	-	-	0,8057
Patients with at least one SAE	Gender	Male	SVd Arm	Infections and infestations	Pneumonia	115	14	12,17	101	87,83	NA	NA	NA	1,07	0,50	2,28	0,8657	0,8057
Patients with at least one SAE	Gender	Male	Vd Arm	Infections and infestations	Pneumonia	113	13	11,50	100	88,50	NA	NA	NA	-	-	-	-	0,8057
Patients with at least one SAE	Age Group	<65	SVd Arm	Infections and infestations	Pneumonia	86	13	15,12	73	84,88	NA	NA	NA	1,91	0,74	4,91	0,1738	0,1123
Patients with at least one SAE	Age Group	<65	Vd Arm	Infections and infestations	Pneumonia	75	7	9,33	68	90,67	NA	NA	NA	-	-	-	-	0,1123
Patients with at least one SAE	Age Group	>=65	SVd Arm	Infections and infestations	Pneumonia	109	11	10,09	98	89,91	NA	NA	NA	0,72	0,34	1,52	0,3840	0,1123
Patients with at least one SAE	Age Group	>=65	Vd Arm	Infections and infestations	Pneumonia	129	18	13,95	111	86,05	NA	NA	NA	-	-	-	-	0,1123
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Pneumonia	173	22	12,72	151	87,28	NA	NA	NA	1,05	0,57	1,93	0,8752	0,9982
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Pneumonia	174	21	12,07	153	87,93	NA	NA	NA	-	-	-	-	0,9982
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Pneumonia	12	2	16,67	10	83,33	NA	NA	NA	1,05	0,13	8,20	0,9649	0,9982
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Pneumonia	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,9982
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Pneumonia	163	14	8,59	149	91,41	NA	NA	NA	0,68	0,34	1,35	0,2701	0,0283
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Pneumonia	173	21	12,14	152	87,86	NA	NA	NA	-	-	-	-	0,0283
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Pneumonia	32	10	31,25	22	68,75	NA	7,00	NA	3,17	0,96	10,43	0,0468	0,0283
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Pneumonia	31	4	12,90	27	87,10	NA	20,90	NA	-	-	-	-	0,0283
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Pneumonia	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,7258
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Pneumonia	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,7258
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Pneumonia	61	6	9,84	55	90,16	NA	34,50	NA	1,06	0,28	4,01	0,9319	0,7258
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Pneumonia	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,7258
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Pneumonia	47	7	14,89	40	85,11	NA	NA	NA	1,27	0,39	4,16	0,6884	0,7258

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Pneumonia	53	6	11,32	47	88,68	NA	NA	NA	-	-	-	-	0,7258
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Pneumonia	69	10	14,49	59	85,51	NA	NA	NA	0,73	0,32	1,65	0,4472	0,7258
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Pneumonia	70	14	20,00	56	80,00	NA	NA	NA	-	-	-	-	0,7258
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Pneumonia	117	12	10,26	105	89,74	NA	NA	NA	1,09	0,48	2,47	0,8426	0,5776
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Pneumonia	136	12	8,82	124	91,18	NA	NA	NA	-	-	-	-	0,5776
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Pneumonia	78	12	15,38	66	84,62	NA	NA	NA	0,79	0,36	1,73	0,5499	0,5776
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Pneumonia	68	13	19,12	55	80,88	NA	NA	NA	-	-	-	-	0,5776
Patients with at least one SAE	Race	Races other than White	SVd Arm	Infections and infestations	Pneumonia	34	4	11,76	30	88,24	NA	NA	NA	1,65	0,34	7,95	0,5296	0,4838
Patients with at least one SAE	Race	Races other than White	Vd Arm	Infections and infestations	Pneumonia	42	3	7,14	39	92,86	NA	NA	NA	-	-	-	-	0,4838
Patients with at least one SAE	Race	White	SVd Arm	Infections and infestations	Pneumonia	161	20	12,42	141	87,58	NA	NA	NA	0,90	0,49	1,68	0,7436	0,4838
Patients with at least one SAE	Race	White	Vd Arm	Infections and infestations	Pneumonia	162	22	13,58	140	86,42	NA	NA	NA	-	-	-	-	0,4838
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Pneumonia	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Pneumonia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Pneumonia	171	21	12,28	150	87,72	NA	NA	NA	0,95	0,53	1,73	0,8747	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Pneumonia	185	24	12,97	161	87,03	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	Infections and infestations	Pneumonia	48	6	12,50	42	87,50	NA	NA	NA	1,43	0,40	5,15	0,5846	0,5683
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	Infections and infestations	Pneumonia	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,5683
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	Infections and infestations	Pneumonia	147	18	12,24	129	87,76	NA	NA	NA	0,94	0,50	1,78	0,8515	0,5683
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	Infections and infestations	Pneumonia	157	21	13,38	136	86,62	NA	NA	NA	-	-	-	-	0,5683

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Pneumonia	98	15	15,31	83	84,69	NA	34,50	NA	1,31	0,62	2,77	0,4776	0,3218
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Pneumonia	104	13	12,50	91	87,50	NA	NA	NA	-	-	-	-	0,3218
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Pneumonia	97	9	9,28	88	90,72	NA	NA	NA	0,73	0,31	1,76	0,4835	0,3218
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Pneumonia	100	12	12,00	88	88,00	NA	NA	NA	-	-	-	-	0,3218
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Pneumonia	98	11	11,22	87	88,78	NA	NA	NA	1,01	0,45	2,27	0,9774	0,9744
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Pneumonia	111	13	11,71	98	88,29	NA	NA	NA	-	-	-	-	0,9744
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Pneumonia	97	13	13,40	84	86,60	NA	NA	NA	1,03	0,46	2,32	0,9414	0,9744
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Pneumonia	93	12	12,90	81	87,10	NA	NA	NA	-	-	-	-	0,9744
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Pneumonia	61	8	13,11	53	86,89	NA	34,50	NA	1,43	0,40	5,15	0,5846	0,4633
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Pneumonia	62	4	6,45	58	93,55	NA	NA	NA	-	-	-	-	0,4633
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Pneumonia	134	16	11,94	118	88,06	NA	NA	NA	0,83	0,43	1,61	0,5842	0,4633
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Pneumonia	142	21	14,79	121	85,21	NA	NA	NA	-	-	-	-	0,4633
Patients with at least one AE	total	-	SVd Arm	Metabolism and nutrition disorders	-	195	108	55,38	87	44,62	4,73	3,12	10,38	2,53	1,82	3,51	0,0000	NA
Patients with at least one AE	total	-	Vd Arm	Metabolism and nutrition disorders	-	204	55	26,96	149	73,04	NA	24,41	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Nervous system disorders	Polyneuropathy	80	6	7,50	74	92,50	NA	NA	NA	0,70	0,20	2,45	0,5771	0,7813
Patients with at least one AE	Gender	Female	Vd Arm	Nervous system disorders	Polyneuropathy	91	7	7,69	84	92,31	NA	NA	NA	-	-	-	-	0,7813
Patients with at least one AE	Gender	Male	SVd Arm	Nervous system disorders	Polyneuropathy	115	6	5,22	109	94,78	NA	NA	NA	0,89	0,29	2,69	0,8354	0,7813
Patients with at least one AE	Gender	Male	Vd Arm	Nervous system disorders	Polyneuropathy	113	7	6,19	106	93,81	NA	NA	NA	-	-	-	-	0,7813
Patients with at least one AE	Age Group	<65	SVd Arm	Nervous system disorders	Polyneuropathy	86	5	5,81	81	94,19	NA	NA	NA	0,51	0,14	1,82	0,2939	0,1959
Patients with at least one AE	Age Group	<65	Vd Arm	Nervous system disorders	Polyneuropathy	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,1959

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	>=65	SVd Arm	Nervous system disorders	Polyneuropathy	109	7	6,42	102	93,58	NA	NA	NA	1,56	0,51	4,73	0,4303	0,1959
Patients with at least one AE	Age Group	>=65	Vd Arm	Nervous system disorders	Polyneuropathy	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	0,1959
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Polyneuropathy	173	11	6,36	162	93,64	NA	NA	NA	0,89	0,39	2,02	0,7826	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Polyneuropathy	174	13	7,47	161	92,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	Polyneuropathy	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	Polyneuropathy	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	Polyneuropathy	163	10	6,13	153	93,87	NA	NA	NA	0,86	0,36	2,07	0,7375	0,5754
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	Polyneuropathy	173	11	6,36	162	93,64	NA	NA	NA	-	-	-	-	0,5754
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	Polyneuropathy	32	2	6,25	30	93,75	NA	25,79	NA	1,60	0,22	11,67	0,6395	0,5754
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	Polyneuropathy	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,5754
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	Polyneuropathy	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,9589
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	Polyneuropathy	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,9589
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	Polyneuropathy	61	3	4,92	58	95,08	NA	NA	NA	0,94	0,13	6,89	0,9504	0,9589
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	Polyneuropathy	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	0,9589
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	Polyneuropathy	47	5	10,64	42	89,36	NA	NA	NA	1,28	0,33	4,98	0,7186	0,9589
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	Polyneuropathy	53	6	11,32	47	88,68	NA	NA	NA	-	-	-	-	0,9589
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	Polyneuropathy	69	4	5,80	65	94,20	NA	NA	NA	1,03	0,27	3,94	0,9709	0,9589
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	Polyneuropathy	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,9589
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	Polyneuropathy	117	8	6,84	109	93,16	NA	NA	NA	1,07	0,39	2,90	0,8965	0,6869
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	Polyneuropathy	136	9	6,62	127	93,38	NA	NA	NA	-	-	-	-	0,6869
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	Polyneuropathy	78	4	5,13	74	94,87	NA	NA	NA	0,74	0,17	3,20	0,6885	0,6869
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	Polyneuropathy	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,6869

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	Races other than White	SVd Arm	Nervous system disorders	Polyneuropathy	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Nervous system disorders	Polyneuropathy	42	3	7,14	39	92,86	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Nervous system disorders	Polyneuropathy	161	11	6,83	150	93,17	NA	NA	NA	1,11	0,46	2,69	0,8136	NA
Patients with at least one AE	Race	White	Vd Arm	Nervous system disorders	Polyneuropathy	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Polyneuropathy	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Polyneuropathy	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	Polyneuropathy	171	10	5,85	161	94,15	NA	NA	NA	0,86	0,37	1,97	0,7177	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	Polyneuropathy	185	14	7,57	171	92,43	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Nervous system disorders	Polyneuropathy	48	2	4,17	46	95,83	NA	NA	NA	0,66	0,10	4,14	0,6513	0,7013
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Nervous system disorders	Polyneuropathy	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,7013
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Nervous system disorders	Polyneuropathy	147	10	6,80	137	93,20	NA	NA	NA	0,98	0,41	2,33	0,9575	0,7013
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Nervous system disorders	Polyneuropathy	157	11	7,01	146	92,99	NA	NA	NA	-	-	-	-	0,7013
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	Polyneuropathy	98	4	4,08	94	95,92	NA	NA	NA	0,66	0,19	2,30	0,5142	0,5151
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	Polyneuropathy	104	7	6,73	97	93,27	NA	NA	NA	-	-	-	-	0,5151
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	Polyneuropathy	97	8	8,25	89	91,75	NA	NA	NA	1,13	0,40	3,19	0,8114	0,5151
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	Polyneuropathy	100	7	7,00	93	93,00	NA	NA	NA	-	-	-	-	0,5151
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	Polyneuropathy	98	6	6,12	92	93,88	NA	NA	NA	0,59	0,21	1,69	0,3196	0,2227
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	Polyneuropathy	111	10	9,01	101	90,99	NA	NA	NA	-	-	-	-	0,2227
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	Polyneuropathy	97	6	6,19	91	93,81	NA	NA	NA	1,76	0,43	7,23	0,4265	0,2227

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	Polyneuropathy	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,2227
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	Polyneuropathy	61	5	8,20	56	91,80	NA	NA	NA	1,00	0,23	4,36	0,9953	0,7861
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	Polyneuropathy	62	4	6,45	58	93,55	NA	NA	NA	-	-	-	-	0,7861
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	Polyneuropathy	134	7	5,22	127	94,78	NA	NA	NA	0,78	0,29	2,09	0,6178	0,7861
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	Polyneuropathy	142	10	7,04	132	92,96	NA	NA	NA	-	-	-	-	0,7861
Patients with at least one AE	total	-	SVd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	195	13	6,67	182	93,33	NA	NA	NA	0,69	0,34	1,40	0,2999	NA
Patients with at least one AE	total	-	Vd Arm	Musculoskeletal and connective tissue disorders	Arthralgia	204	20	9,80	184	90,20	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	General disorders and administration site conditions	Pyrexia	80	12	15,00	68	85,00	NA	NA	NA	2,19	0,81	5,92	0,1118	0,2197
Patients with at least one AE	Gender	Female	Vd Arm	General disorders and administration site conditions	Pyrexia	91	7	7,69	84	92,31	NA	NA	NA	-	-	-	-	0,2197
Patients with at least one AE	Gender	Male	SVd Arm	General disorders and administration site conditions	Pyrexia	115	19	16,52	96	83,48	NA	NA	NA	1,05	0,55	1,99	0,8896	0,2197
Patients with at least one AE	Gender	Male	Vd Arm	General disorders and administration site conditions	Pyrexia	113	19	16,81	94	83,19	NA	24,54	NA	-	-	-	-	0,2197
Patients with at least one AE	Age Group	<65	SVd Arm	General disorders and administration site conditions	Pyrexia	86	22	25,58	64	74,42	NA	NA	NA	3,20	1,28	7,99	0,0089	0,0058
Patients with at least one AE	Age Group	<65	Vd Arm	General disorders and administration site conditions	Pyrexia	75	7	9,33	68	90,67	NA	NA	NA	-	-	-	-	0,0058
Patients with at least one AE	Age Group	>=65	SVd Arm	General disorders and administration site conditions	Pyrexia	109	9	8,26	100	91,74	NA	NA	NA	0,58	0,26	1,28	0,1719	0,0058
Patients with at least one AE	Age Group	>=65	Vd Arm	General disorders and administration site conditions	Pyrexia	129	19	14,73	110	85,27	NA	25,46	NA	-	-	-	-	0,0058
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Pyrexia	173	25	14,45	148	85,55	NA	NA	NA	1,05	0,59	1,84	0,8779	0,2666

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Pyrexia	174	24	13,79	150	86,21	NA	25,46	NA	-	-	-	-	0,2666
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Pyrexia	12	4	33,33	8	66,67	NA	3,58	NA	3,95	0,41	38,59	0,2096	0,2666
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Pyrexia	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,2666
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	Pyrexia	163	25	15,34	138	84,66	NA	NA	NA	1,22	0,69	2,18	0,4959	0,4729
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	Pyrexia	173	22	12,72	151	87,28	NA	NA	NA	-	-	-	-	0,4729
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	Pyrexia	32	6	18,75	26	81,25	NA	NA	NA	2,15	0,52	8,93	0,2840	0,4729
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	Pyrexia	31	4	12,90	27	87,10	NA	20,67	NA	-	-	-	-	0,4729
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	General disorders and administration site conditions	Pyrexia	18	5	27,78	13	72,22	NA	6,01	NA	4,42	0,51	38,41	0,1424	0,5796
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	General disorders and administration site conditions	Pyrexia	17	2	11,76	15	88,24	NA	10,38	NA	-	-	-	-	0,5796
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	General disorders and administration site conditions	Pyrexia	61	7	11,48	54	88,52	NA	NA	NA	1,13	0,40	3,19	0,8130	0,5796
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	General disorders and administration site conditions	Pyrexia	64	8	12,50	56	87,50	NA	NA	NA	-	-	-	-	0,5796
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	General disorders and administration site conditions	Pyrexia	47	3	6,38	44	93,62	NA	NA	NA	0,62	0,10	3,81	0,5994	0,5796
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	General disorders and administration site conditions	Pyrexia	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,5796
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	General disorders and administration site conditions	Pyrexia	69	16	23,19	53	76,81	NA	NA	NA	1,38	0,66	2,88	0,3892	0,5796
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	General disorders and administration site conditions	Pyrexia	70	13	18,57	57	81,43	NA	24,54	NA	-	-	-	-	0,5796
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	General disorders and administration site conditions	Pyrexia	117	15	12,82	102	87,18	NA	NA	NA	1,56	0,69	3,48	0,2798	0,4567

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	General disorders and administration site conditions	Pyrexia	136	11	8,09	125	91,91	NA	NA	NA	-	-	-	-	0,4567
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	General disorders and administration site conditions	Pyrexia	78	16	20,51	62	79,49	NA	NA	NA	1,03	0,51	2,11	0,9274	0,4567
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	General disorders and administration site conditions	Pyrexia	68	15	22,06	53	77,94	NA	20,86	NA	-	-	-	-	0,4567
Patients with at least one AE	Race	Races other than White	SVd Arm	General disorders and administration site conditions	Pyrexia	34	11	32,35	23	67,65	NA	9,56	NA	1,19	0,47	3,00	0,7125	0,7621
Patients with at least one AE	Race	Races other than White	Vd Arm	General disorders and administration site conditions	Pyrexia	42	12	28,57	30	71,43	24,54	20,86	NA	-	-	-	-	0,7621
Patients with at least one AE	Race	White	SVd Arm	General disorders and administration site conditions	Pyrexia	161	20	12,42	141	87,58	NA	NA	NA	1,42	0,71	2,85	0,3178	0,7621
Patients with at least one AE	Race	White	Vd Arm	General disorders and administration site conditions	Pyrexia	162	14	8,64	148	91,36	NA	NA	NA	-	-	-	-	0,7621
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Pyrexia	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Pyrexia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	Pyrexia	171	25	14,62	146	85,38	NA	NA	NA	1,17	0,67	2,04	0,5893	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	Pyrexia	185	25	13,51	160	86,49	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	General disorders and administration site conditions	Pyrexia	48	9	18,75	39	81,25	NA	NA	NA	1,51	0,53	4,27	0,4346	0,7326
Patients with at least one AE	Prior PI therapies	N	Vd Arm	General disorders and administration site conditions	Pyrexia	47	6	12,77	41	87,23	NA	NA	NA	-	-	-	-	0,7326
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	General disorders and administration site conditions	Pyrexia	147	22	14,97	125	85,03	NA	NA	NA	1,22	0,66	2,25	0,5170	0,7326
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	General disorders and administration site conditions	Pyrexia	157	20	12,74	137	87,26	NA	NA	NA	-	-	-	-	0,7326

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	General disorders and administration site conditions	Pyrexia	98	15	15,31	83	84,69	NA	NA	NA	1,01	0,50	2,06	0,9763	0,3185
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	General disorders and administration site conditions	Pyrexia	104	16	15,38	88	84,62	NA	24,54	NA	-	-	-	-	0,3185
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	General disorders and administration site conditions	Pyrexia	97	16	16,49	81	83,51	NA	NA	NA	1,74	0,79	3,85	0,1669	0,3185
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	General disorders and administration site conditions	Pyrexia	100	10	10,00	90	90,00	NA	NA	NA	-	-	-	-	0,3185
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	General disorders and administration site conditions	Pyrexia	98	18	18,37	80	81,63	NA	NA	NA	1,32	0,67	2,60	0,4256	0,9309
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	General disorders and administration site conditions	Pyrexia	111	17	15,32	94	84,68	NA	24,54	NA	-	-	-	-	0,9309
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	General disorders and administration site conditions	Pyrexia	97	13	13,40	84	86,60	NA	NA	NA	1,26	0,53	2,96	0,6035	0,9309
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	General disorders and administration site conditions	Pyrexia	93	9	9,68	84	90,32	NA	NA	NA	-	-	-	-	0,9309
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	General disorders and administration site conditions	Pyrexia	61	11	18,03	50	81,97	NA	NA	NA	1,68	0,65	4,36	0,2834	0,5908
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	General disorders and administration site conditions	Pyrexia	62	7	11,29	55	88,71	NA	NA	NA	-	-	-	-	0,5908
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	General disorders and administration site conditions	Pyrexia	134	20	14,93	114	85,07	NA	NA	NA	1,22	0,65	2,32	0,5337	0,5908
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	General disorders and administration site conditions	Pyrexia	142	19	13,38	123	86,62	NA	NA	NA	-	-	-	-	0,5908
Patients with at least one AE	total	-	SVd Arm	Musculoskeletal and connective tissue disorders	Back pain	195	30	15,38	165	84,62	NA	NA	NA	1,12	0,67	1,87	0,6712	NA
Patients with at least one AE	total	-	Vd Arm	Musculoskeletal and connective tissue disorders	Back pain	204	29	14,22	175	85,78	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Skin and subcutaneous tissue disorders	Rash	80	2	2,50	78	97,50	NA	NA	NA	0,74	0,11	4,78	0,7514	0,7561
Patients with at least one AE	Gender	Female	Vd Arm	Skin and subcutaneous tissue disorders	Rash	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,7561
Patients with at least one AE	Gender	Male	SVd Arm	Skin and subcutaneous tissue disorders	Rash	115	4	3,48	111	96,52	NA	NA	NA	0,52	0,15	1,80	0,2924	0,7561

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Male	Vd Arm	Skin and subcutaneous tissue disorders	Rash	113	7	6,19	106	93,81	NA	NA	NA	-	-	-	-	0,7561
Patients with at least one AE	Age Group	<65	SVd Arm	Skin and subcutaneous tissue disorders	Rash	86	3	3,49	83	96,51	NA	NA	NA	0,65	0,15	2,76	0,5524	0,8626
Patients with at least one AE	Age Group	<65	Vd Arm	Skin and subcutaneous tissue disorders	Rash	75	5	6,67	70	93,33	NA	NA	NA	-	-	-	-	0,8626
Patients with at least one AE	Age Group	>=65	SVd Arm	Skin and subcutaneous tissue disorders	Rash	109	3	2,75	106	97,25	NA	NA	NA	0,77	0,18	3,28	0,7277	0,8626
Patients with at least one AE	Age Group	>=65	Vd Arm	Skin and subcutaneous tissue disorders	Rash	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	0,8626
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Skin and subcutaneous tissue disorders	Rash	173	4	2,31	169	97,69	NA	NA	NA	0,51	0,15	1,68	0,2575	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Skin and subcutaneous tissue disorders	Rash	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Skin and subcutaneous tissue disorders	Rash	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Skin and subcutaneous tissue disorders	Rash	16	1	6,25	15	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Skin and subcutaneous tissue disorders	Rash	163	5	3,07	158	96,93	NA	NA	NA	0,61	0,20	1,82	0,3691	0,4924
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Skin and subcutaneous tissue disorders	Rash	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	0,4924
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Skin and subcutaneous tissue disorders	Rash	32	1	3,12	31	96,88	NA	NA	NA	1,73	0,11	27,89	0,6949	0,4924
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Skin and subcutaneous tissue disorders	Rash	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,4924
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Skin and subcutaneous tissue disorders	Rash	18	1	5,56	17	94,44	NA	NA	NA	0,40	0,04	4,48	0,4451	0,8275
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Skin and subcutaneous tissue disorders	Rash	17	3	17,65	14	82,35	NA	11,04	NA	-	-	-	-	0,8275
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Skin and subcutaneous tissue disorders	Rash	61	3	4,92	58	95,08	NA	NA	NA	0,38	0,10	1,49	0,1499	0,8275
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Skin and subcutaneous tissue disorders	Rash	64	7	10,94	57	89,06	NA	32,20	NA	-	-	-	-	0,8275
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Skin and subcutaneous tissue disorders	Rash	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,8275
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Skin and subcutaneous tissue disorders	Rash	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,8275
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Skin and subcutaneous tissue disorders	Rash	69	1	1,45	68	98,55	NA	NA	NA	0,99	0,06	15,96	0,9965	0,8275
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Skin and subcutaneous tissue disorders	Rash	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,8275
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Skin and subcutaneous tissue disorders	Rash	117	5	4,27	112	95,73	NA	NA	NA	0,63	0,21	1,91	0,4072	0,7213
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Skin and subcutaneous tissue disorders	Rash	136	9	6,62	127	93,38	NA	NA	NA	-	-	-	-	0,7213

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Skin and subcutaneous tissue disorders	Rash	78	1	1,28	77	98,72	NA	NA	NA	0,39	0,04	4,28	0,4221	0,7213
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Skin and subcutaneous tissue disorders	Rash	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,7213
Patients with at least one AE	Race	Races other than White	SVd Arm	Skin and subcutaneous tissue disorders	Rash	34	1	2,94	33	97,06	NA	NA	NA	0,46	0,04	4,72	0,5026	0,7641
Patients with at least one AE	Race	Races other than White	Vd Arm	Skin and subcutaneous tissue disorders	Rash	42	3	7,14	39	92,86	NA	NA	NA	-	-	-	-	0,7641
Patients with at least one AE	Race	White	SVd Arm	Skin and subcutaneous tissue disorders	Rash	161	5	3,11	156	96,89	NA	NA	NA	0,68	0,22	2,13	0,5072	0,7641
Patients with at least one AE	Race	White	Vd Arm	Skin and subcutaneous tissue disorders	Rash	162	8	4,94	154	95,06	NA	NA	NA	-	-	-	-	0,7641
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Skin and subcutaneous tissue disorders	Rash	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Skin and subcutaneous tissue disorders	Rash	5	1	20,00	4	80,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Skin and subcutaneous tissue disorders	Rash	171	5	2,92	166	97,08	NA	NA	NA	0,62	0,21	1,83	0,3791	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Skin and subcutaneous tissue disorders	Rash	185	10	5,41	175	94,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Skin and subcutaneous tissue disorders	Rash	48	3	6,25	45	93,75	NA	NA	NA	1,78	0,29	10,82	0,5271	0,1932
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Skin and subcutaneous tissue disorders	Rash	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,1932
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Skin and subcutaneous tissue disorders	Rash	147	3	2,04	144	97,96	NA	NA	NA	0,40	0,11	1,51	0,1642	0,1932
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Skin and subcutaneous tissue disorders	Rash	157	9	5,73	148	94,27	NA	NA	NA	-	-	-	-	0,1932
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Skin and subcutaneous tissue disorders	Rash	98	2	2,04	96	97,96	NA	NA	NA	0,27	0,06	1,27	0,0765	0,0674
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Skin and subcutaneous tissue disorders	Rash	104	9	8,65	95	91,35	NA	NA	NA	-	-	-	-	0,0674
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Skin and subcutaneous tissue disorders	Rash	97	4	4,12	93	95,88	NA	NA	NA	2,33	0,42	12,93	0,3205	0,0674
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Skin and subcutaneous tissue disorders	Rash	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,0674
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Skin and subcutaneous tissue disorders	Rash	98	6	6,12	92	93,88	NA	NA	NA	1,36	0,43	4,32	0,6009	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Skin and subcutaneous tissue disorders	Rash	111	6	5,41	105	94,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Skin and subcutaneous tissue disorders	Rash	97	0	0,00	97	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Skin and subcutaneous tissue disorders	Rash	93	5	5,38	88	94,62	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Skin and subcutaneous tissue disorders	Rash	61	3	4,92	58	95,08	NA	NA	NA	1,25	0,25	6,28	0,7885	0,4177
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Skin and subcutaneous tissue disorders	Rash	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,4177
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Skin and subcutaneous tissue disorders	Rash	134	3	2,24	131	97,76	NA	NA	NA	0,52	0,13	2,06	0,3418	0,4177
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Skin and subcutaneous tissue disorders	Rash	142	8	5,63	134	94,37	NA	NA	NA	-	-	-	-	0,4177
Patients with at least one AE	total	-	SVd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	195	7	3,59	188	96,41	NA	NA	NA	0,46	0,17	1,21	0,1083	NA
Patients with at least one AE	total	-	Vd Arm	Musculoskeletal and connective tissue disorders	Muscle spasms	204	12	5,88	192	94,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Infections and infestations	Respiratory tract infection	80	6	7,50	74	92,50	NA	NA	NA	2,11	0,52	8,59	0,2882	0,9059
Patients with at least one AE	Gender	Female	Vd Arm	Infections and infestations	Respiratory tract infection	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,9059
Patients with at least one AE	Gender	Male	SVd Arm	Infections and infestations	Respiratory tract infection	115	10	8,70	105	91,30	NA	44,16	NA	1,89	0,63	5,69	0,2482	0,9059
Patients with at least one AE	Gender	Male	Vd Arm	Infections and infestations	Respiratory tract infection	113	5	4,42	108	95,58	NA	NA	NA	-	-	-	-	0,9059
Patients with at least one AE	Age Group	<65	SVd Arm	Infections and infestations	Respiratory tract infection	86	7	8,14	79	91,86	NA	NA	NA	1,55	0,40	6,07	0,5266	0,8240
Patients with at least one AE	Age Group	<65	Vd Arm	Infections and infestations	Respiratory tract infection	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,8240
Patients with at least one AE	Age Group	>=65	SVd Arm	Infections and infestations	Respiratory tract infection	109	9	8,26	100	91,74	NA	44,16	NA	1,89	0,61	5,84	0,2582	0,8240
Patients with at least one AE	Age Group	>=65	Vd Arm	Infections and infestations	Respiratory tract infection	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	0,8240
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Respiratory tract infection	173	14	8,09	159	91,91	NA	44,16	NA	1,62	0,67	3,92	0,2829	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Respiratory tract infection	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Respiratory tract infection	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Respiratory tract infection	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Respiratory tract infection	163	16	9,82	147	90,18	NA	44,16	NA	1,97	0,83	4,67	0,1156	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Respiratory tract infection	173	8	4,62	165	95,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Respiratory tract infection	32	0	0,00	32	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Respiratory tract infection	31	0	0,00	31	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Respiratory tract infection	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,6135
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Respiratory tract infection	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,6135
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Respiratory tract infection	61	7	11,48	54	88,52	44,16	NA	NA	1,54	0,43	5,47	0,5020	0,6135
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Respiratory tract infection	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,6135
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Respiratory tract infection	47	3	6,38	44	93,62	NA	NA	NA	0,91	0,18	4,54	0,9059	0,6135
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Respiratory tract infection	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,6135
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Respiratory tract infection	69	5	7,25	64	92,75	-	-	-	-	-	-	-	0,6135
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Respiratory tract infection	70	0	0,00	70	100,00	-	-	-	-	-	-	-	0,6135
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Respiratory tract infection	117	12	10,26	105	89,74	NA	44,16	NA	1,45	0,58	3,65	0,4240	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Respiratory tract infection	136	8	5,88	128	94,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Respiratory tract infection	78	4	5,13	74	94,87	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Respiratory tract infection	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	SVd Arm	Infections and infestations	Respiratory tract infection	34	1	2,94	33	97,06	NA	NA	NA	0,89	0,06	14,36	0,9372	0,6017
Patients with at least one AE	Race	Races other than White	Vd Arm	Infections and infestations	Respiratory tract infection	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,6017
Patients with at least one AE	Race	White	SVd Arm	Infections and infestations	Respiratory tract infection	161	15	9,32	146	90,68	NA	44,16	NA	1,95	0,78	4,90	0,1491	0,6017
Patients with at least one AE	Race	White	Vd Arm	Infections and infestations	Respiratory tract infection	162	7	4,32	155	95,68	NA	NA	NA	-	-	-	-	0,6017
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Respiratory tract infection	6	1	16,67	5	83,33	NA	NA	NA	0,47	0,03	7,86	0,5924	0,3079

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Respiratory tract infection	5	1	20,00	4	80,00	NA	NA	NA	-	-	-	-	0,3079
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Respiratory tract infection	171	15	8,77	156	91,23	NA	44,16	NA	2,20	0,88	5,47	0,0832	0,3079
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Respiratory tract infection	185	7	3,78	178	96,22	NA	NA	NA	-	-	-	-	0,3079
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Infections and infestations	Respiratory tract infection	48	4	8,33	44	91,67	NA	NA	NA	4,20	0,47	37,73	0,1636	0,4407
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Infections and infestations	Respiratory tract infection	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,4407
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Infections and infestations	Respiratory tract infection	147	12	8,16	135	91,84	NA	44,16	NA	1,64	0,63	4,24	0,3033	0,4407
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Infections and infestations	Respiratory tract infection	157	7	4,46	150	95,54	NA	NA	NA	-	-	-	-	0,4407
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Respiratory tract infection	98	9	9,18	89	90,82	44,16	NA	NA	2,85	0,75	10,78	0,1067	0,4439
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Respiratory tract infection	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,4439
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Respiratory tract infection	97	7	7,22	90	92,78	NA	NA	NA	1,43	0,45	4,53	0,5378	0,4439
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Respiratory tract infection	100	5	5,00	95	95,00	NA	NA	NA	-	-	-	-	0,4439
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Respiratory tract infection	98	9	9,18	89	90,82	44,16	44,16	NA	3,19	0,84	12,13	0,0724	0,2673
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Respiratory tract infection	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	0,2673
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Respiratory tract infection	97	7	7,22	90	92,78	NA	NA	NA	1,17	0,37	3,75	0,7902	0,2673
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Respiratory tract infection	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,2673
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Respiratory tract infection	61	4	6,56	57	93,44	NA	NA	NA	2,14	0,39	11,75	0,3683	0,9245
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Respiratory tract infection	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,9245
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Respiratory tract infection	134	12	8,96	122	91,04	NA	44,16	NA	1,95	0,72	5,30	0,1830	0,9245

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Respiratory tract infection	142	6	4,23	136	95,77	NA	NA	NA	-	-	-	-	0,9245
Patients with at least one AE	total	-	SVd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	195	10	5,13	185	94,87	NA	NA	NA	0,63	0,29	1,37	0,2388	NA
Patients with at least one AE	total	-	Vd Arm	Musculoskeletal and connective tissue disorders	Pain in extremity	204	17	8,33	187	91,67	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Cardiac disorders	Tachycardia	80	5	6,25	75	93,75	NA	NA	NA	2,65	0,50	14,02	0,2335	0,5967
Patients with at least one AE	Gender	Female	Vd Arm	Cardiac disorders	Tachycardia	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,5967
Patients with at least one AE	Gender	Male	SVd Arm	Cardiac disorders	Tachycardia	115	5	4,35	110	95,65	NA	NA	NA	5,54	0,64	47,72	0,0803	0,5967
Patients with at least one AE	Gender	Male	Vd Arm	Cardiac disorders	Tachycardia	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	0,5967
Patients with at least one AE	Age Group	<65	SVd Arm	Cardiac disorders	Tachycardia	86	7	8,14	79	91,86	NA	NA	NA	2,67	0,55	13,07	0,2072	0,9208
Patients with at least one AE	Age Group	<65	Vd Arm	Cardiac disorders	Tachycardia	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,9208
Patients with at least one AE	Age Group	>=65	SVd Arm	Cardiac disorders	Tachycardia	109	3	2,75	106	97,25	NA	NA	NA	3,08	0,32	29,93	0,3083	0,9208
Patients with at least one AE	Age Group	>=65	Vd Arm	Cardiac disorders	Tachycardia	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	0,9208
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Cardiac disorders	Tachycardia	173	7	4,05	166	95,95	NA	NA	NA	3,64	0,75	17,61	0,0863	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Cardiac disorders	Tachycardia	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Cardiac disorders	Tachycardia	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Cardiac disorders	Tachycardia	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Cardiac disorders	Tachycardia	163	7	4,29	156	95,71	NA	NA	NA	2,39	0,62	9,27	0,1930	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Cardiac disorders	Tachycardia	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Cardiac disorders	Tachycardia	32	3	9,38	29	90,62	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Cardiac disorders	Tachycardia	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Cardiac disorders	Tachycardia	18	2	11,11	16	88,89	-	-	-	-	-	-	-	0,3463
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Cardiac disorders	Tachycardia	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,3463
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Cardiac disorders	Tachycardia	61	2	3,28	59	96,72	NA	NA	NA	1,10	0,15	7,83	0,9246	0,3463
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Cardiac disorders	Tachycardia	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	0,3463
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Cardiac disorders	Tachycardia	47	2	4,26	45	95,74	-	-	-	-	-	-	-	0,3463
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Cardiac disorders	Tachycardia	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,3463
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Cardiac disorders	Tachycardia	69	4	5,80	65	94,20	NA	NA	NA	4,53	0,50	40,68	0,1395	0,3463
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Cardiac disorders	Tachycardia	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,3463
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Cardiac disorders	Tachycardia	117	6	5,13	111	94,87	NA	NA	NA	7,23	0,87	60,43	0,0330	0,3444
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Cardiac disorders	Tachycardia	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,3444

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Cardiac disorders	Tachycardia	78	4	5,13	74	94,87	NA	NA	NA	1,94	0,35	10,73	0,4385	0,3444
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Cardiac disorders	Tachycardia	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,3444
Patients with at least one AE	Race	Races other than White	SVd Arm	Cardiac disorders	Tachycardia	34	3	8,82	31	91,18	NA	NA	NA	3,72	0,34	41,30	0,2509	0,9552
Patients with at least one AE	Race	Races other than White	Vd Arm	Cardiac disorders	Tachycardia	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,9552
Patients with at least one AE	Race	White	SVd Arm	Cardiac disorders	Tachycardia	161	7	4,35	154	95,65	NA	NA	NA	3,43	0,71	16,65	0,1047	0,9552
Patients with at least one AE	Race	White	Vd Arm	Cardiac disorders	Tachycardia	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	0,9552
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Cardiac disorders	Tachycardia	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Cardiac disorders	Tachycardia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Cardiac disorders	Tachycardia	171	8	4,68	163	95,32	NA	NA	NA	2,81	0,74	10,65	0,1115	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Cardiac disorders	Tachycardia	185	3	1,62	182	98,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Cardiac disorders	Tachycardia	48	0	0,00	48	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Cardiac disorders	Tachycardia	47	1	2,13	46	97,87	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Cardiac disorders	Tachycardia	147	10	6,80	137	93,20	NA	NA	NA	5,16	1,13	23,55	0,0183	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Cardiac disorders	Tachycardia	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Cardiac disorders	Tachycardia	98	3	3,06	95	96,94	NA	NA	NA	1,46	0,24	8,73	0,6777	0,2531
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Cardiac disorders	Tachycardia	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	0,2531
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Cardiac disorders	Tachycardia	97	7	7,22	90	92,78	NA	NA	NA	7,28	0,89	59,26	0,0298	0,2531
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Cardiac disorders	Tachycardia	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,2531
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Cardiac disorders	Tachycardia	98	7	7,14	91	92,86	NA	NA	NA	2,94	0,76	11,45	0,1032	NA
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Cardiac disorders	Tachycardia	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Cardiac disorders	Tachycardia	97	3	3,09	94	96,91	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Cardiac disorders	Tachycardia	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Cardiac disorders	Tachycardia	61	1	1,64	60	98,36	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Cardiac disorders	Tachycardia	62	1	1,61	61	98,39	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Cardiac disorders	Tachycardia	134	9	6,72	125	93,28	NA	NA	NA	4,51	0,97	20,91	0,0345	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Cardiac disorders	Tachycardia	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Musculoskeletal and connective tissue disorders	-	195	77	39,49	118	60,51	22,44	12,12	37,06	1,01	0,73	1,39	0,9549	NA
Patients with at least one AE	total	-	Vd Arm	Musculoskeletal and connective tissue disorders	-	204	80	39,22	124	60,78	16,49	9,46	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	80	41	51,25	39	48,75	4,40	2,10	NA	2,68	1,55	4,65	0,0003	0,3598
Patients with at least one AE	Gender	Female	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	91	23	25,27	68	74,73	NA	20,47	NA	-	-	-	-	0,3598
Patients with at least one AE	Gender	Male	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	115	73	63,48	42	36,52	1,81	1,41	7,43	3,74	2,38	5,88	0,0000	0,3598
Patients with at least one AE	Gender	Male	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	113	27	23,89	86	76,11	NA	NA	NA	-	-	-	-	0,3598
Patients with at least one AE	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	86	51	59,30	35	40,70	4,17	2,10	10,64	2,93	1,71	5,04	0,0000	0,7854
Patients with at least one AE	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	75	19	25,33	56	74,67	NA	NA	NA	-	-	-	-	0,7854
Patients with at least one AE	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	109	63	57,80	46	42,20	1,68	1,41	15,24	3,23	2,08	5,02	0,0000	0,7854
Patients with at least one AE	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	129	31	24,03	98	75,97	NA	NA	NA	-	-	-	-	0,7854
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	173	99	57,23	74	42,77	4,14	1,68	9,99	3,33	2,29	4,84	0,0000	0,3167
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	174	40	22,99	134	77,01	NA	NA	NA	-	-	-	-	0,3167
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	12	10	83,33	2	16,67	1,41	0,95	NA	1,83	0,60	5,55	0,2798	0,3167
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	16	7	43,75	9	56,25	10,97	0,69	NA	-	-	-	-	0,3167

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	163	94	57,67	69	42,33	4,14	1,64	9,79	3,23	2,22	4,71	0,0000	0,7084
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	173	40	23,12	133	76,88	NA	NA	NA	-	-	-	-	0,7084
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	32	20	62,50	12	37,50	2,79	1,41	NA	2,74	1,24	6,03	0,0096	0,7084
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	31	10	32,26	21	67,74	NA	10,97	NA	-	-	-	-	0,7084
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	18	13	72,22	5	27,78	2,99	0,72	NA	5,87	1,25	27,69	0,0129	0,2157
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	17	5	29,41	12	70,59	NA	10,12	NA	-	-	-	-	0,2157
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	61	38	62,30	23	37,70	1,41	1,12	4,14	2,02	1,19	3,41	0,0077	0,2157
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	64	24	37,50	40	62,50	NA	6,24	NA	-	-	-	-	0,2157
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	47	25	53,19	22	46,81	6,93	1,64	NA	4,21	1,88	9,46	0,0002	0,2157
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	53	8	15,09	45	84,91	NA	NA	NA	-	-	-	-	0,2157
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	69	38	55,07	31	44,93	4,17	1,81	NA	4,07	2,15	7,70	0,0000	0,2157
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	70	13	18,57	57	81,43	NA	NA	NA	-	-	-	-	0,2157
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	117	68	58,12	49	41,88	3,71	1,64	9,79	2,68	1,78	4,04	0,0000	0,2028
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	136	37	27,21	99	72,79	NA	NA	NA	-	-	-	-	0,2028
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	78	46	58,97	32	41,03	2,79	1,41	23,26	4,36	2,33	8,12	0,0000	0,2028
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	68	13	19,12	55	80,88	NA	NA	NA	-	-	-	-	0,2028
Patients with at least one AE	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	34	18	52,94	16	47,06	4,14	1,68	NA	3,62	1,45	9,05	0,0035	0,6652
Patients with at least one AE	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	42	8	19,05	34	80,95	NA	NA	NA	-	-	-	-	0,6652
Patients with at least one AE	Race	White	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	161	96	59,63	65	40,37	3,32	1,41	8,34	2,91	2,02	4,20	0,0000	0,6652
Patients with at least one AE	Race	White	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	162	42	25,93	120	74,07	NA	NA	NA	-	-	-	-	0,6652
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	6	5	83,33	1	16,67	0,82	0,26	NA	2,88	0,32	26,18	0,3270	0,9266

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	5	2	40,00	3	60,00	NA	1,05	NA	-	-	-	-	0,9266
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	171	100	58,48	71	41,52	3,78	1,68	8,34	3,20	2,23	4,57	0,0000	0,9266
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	185	45	24,32	140	75,68	NA	NA	NA	-	-	-	-	0,9266
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	48	27	56,25	21	43,75	4,86	2,10	NA	3,77	1,76	8,09	0,0003	0,6025
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	47	9	19,15	38	80,85	NA	NA	NA	-	-	-	-	0,6025
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	147	87	59,18	60	40,82	2,79	1,41	8,34	3,01	2,06	4,39	0,0000	0,6025
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	157	41	26,11	116	73,89	NA	NA	NA	-	-	-	-	0,6025
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	98	58	59,18	40	40,82	3,78	1,41	10,64	3,91	2,36	6,48	0,0000	0,2411
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	104	22	21,15	82	78,85	NA	NA	NA	-	-	-	-	0,2411
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	97	56	57,73	41	42,27	2,83	1,61	15,24	2,60	1,65	4,11	0,0000	0,2411
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	100	28	28,00	72	72,00	NA	NA	NA	-	-	-	-	0,2411
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	98	53	54,08	45	45,92	4,17	1,68	15,24	3,28	2,00	5,37	0,0000	0,7334
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	111	24	21,62	87	78,38	NA	NA	NA	-	-	-	-	0,7334
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	97	61	62,89	36	37,11	2,63	1,41	6,93	2,91	1,81	4,69	0,0000	0,7334
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	93	26	27,96	67	72,04	NA	NA	NA	-	-	-	-	0,7334
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	61	32	52,46	29	47,54	6,93	2,79	NA	2,87	1,52	5,43	0,0007	0,6861
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	62	14	22,58	48	77,42	NA	NA	NA	-	-	-	-	0,6861
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	134	82	61,19	52	38,81	2,63	1,41	7,43	3,35	2,24	5,01	0,0000	0,6861

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	142	36	25,35	106	74,65	NA	NA	NA	-	-	-	-	0,6861
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	195	78	40,00	117	60,00	30,16	15,44	NA	2,89	1,91	4,37	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	204	32	15,69	172	84,31	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	80	32	40,00	48	60,00	24,48	15,44	NA	3,38	1,68	6,79	0,0003	0,8226
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	91	15	16,48	76	83,52	NA	NA	NA	-	-	-	-	0,8226
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	115	46	40,00	69	60,00	NA	9,79	NA	3,05	1,74	5,34	0,0000	0,8226
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	113	17	15,04	96	84,96	NA	NA	NA	-	-	-	-	0,8226
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	86	35	40,70	51	59,30	30,16	9,92	NA	2,46	1,30	4,66	0,0042	0,5352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	75	14	18,67	61	81,33	NA	NA	NA	-	-	-	-	0,5352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	109	43	39,45	66	60,55	NA	5,09	NA	3,22	1,85	5,61	0,0000	0,5352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	129	18	13,95	111	86,05	NA	NA	NA	-	-	-	-	0,5352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	173	71	41,04	102	58,96	30,16	15,44	NA	3,27	2,07	5,18	0,0000	0,0802
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	174	25	14,37	149	85,63	NA	NA	NA	-	-	-	-	0,0802
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	12	4	33,33	8	66,67	NA	2,10	NA	0,86	0,21	3,57	0,8402	0,0802
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	16	6	37,50	10	62,50	NA	2,37	NA	-	-	-	-	0,0802
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	163	68	41,72	95	58,28	24,48	9,92	NA	3,31	2,07	5,29	0,0000	0,1232

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	173	24	13,87	149	86,13	NA	NA	NA	-	-	-	-	0,1232
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	32	10	31,25	22	68,75	NA	NA	NA	1,45	0,56	3,72	0,4389	0,1232
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	31	8	25,81	23	74,19	NA	NA	NA	-	-	-	-	0,1232
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	18	7	38,89	11	61,11	9,79	2,99	NA	2,20	0,41	11,66	0,3441	0,6876
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	17	5	29,41	12	70,59	NA	10,12	NA	-	-	-	-	0,6876
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	61	30	49,18	31	50,82	5,09	2,79	NA	2,46	1,29	4,66	0,0046	0,6876
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	64	14	21,88	50	78,12	NA	NA	NA	-	-	-	-	0,6876
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	47	17	36,17	30	63,83	NA	16,33	NA	5,17	1,72	15,52	0,0012	0,6876
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,6876
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	69	24	34,78	45	65,22	30,16	24,48	NA	3,21	1,48	6,99	0,0020	0,6876
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	70	9	12,86	61	87,14	NA	NA	NA	-	-	-	-	0,6876
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	117	46	39,32	71	60,68	NA	9,92	NA	2,55	1,54	4,22	0,0002	0,4105
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	136	23	16,91	113	83,09	NA	NA	NA	-	-	-	-	0,4105
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	78	32	41,03	46	58,97	30,16	6,51	NA	3,72	1,76	7,86	0,0002	0,4105
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	68	9	13,24	59	86,76	NA	NA	NA	-	-	-	-	0,4105
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	34	8	23,53	26	76,47	NA	NA	NA	1,75	0,55	5,54	0,3370	0,4420

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,4420
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	161	70	43,48	91	56,52	24,48	9,79	NA	2,84	1,81	4,45	0,0000	0,4420
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	162	27	16,67	135	83,33	NA	NA	NA	-	-	-	-	0,4420
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	171	65	38,01	106	61,99	30,16	16,33	NA	2,62	1,69	4,06	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	185	30	16,22	155	83,78	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	48	17	35,42	31	64,58	30,16	24,48	NA	2,85	1,11	7,34	0,0239	0,9743
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	47	6	12,77	41	87,23	NA	NA	NA	-	-	-	-	0,9743
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	147	61	41,50	86	58,50	18,63	9,92	NA	2,90	1,83	4,60	0,0000	0,9743
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	157	26	16,56	131	83,44	NA	NA	NA	-	-	-	-	0,9743
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	98	39	39,80	59	60,20	16,33	9,79	NA	3,72	1,98	7,00	0,0000	0,2753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	104	13	12,50	91	87,50	NA	NA	NA	-	-	-	-	0,2753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	97	39	40,21	58	59,79	30,16	18,63	NA	2,33	1,34	4,06	0,0021	0,2753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	100	19	19,00	81	81,00	NA	NA	NA	-	-	-	-	0,2753

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	98	31	31,63	67	68,37	NA	30,16	NA	2,25	1,21	4,17	0,0083	0,3914
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	111	16	14,41	95	85,59	NA	NA	NA	-	-	-	-	0,3914
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	97	47	48,45	50	51,55	15,44	4,17	NA	3,26	1,82	5,86	0,0000	0,3914
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	93	16	17,20	77	82,80	NA	NA	NA	-	-	-	-	0,3914
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	61	20	32,79	41	67,21	30,16	24,48	NA	2,62	1,14	6,02	0,0190	0,7228
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	62	8	12,90	54	87,10	NA	NA	NA	-	-	-	-	0,7228
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	Thrombocytopenia	134	58	43,28	76	56,72	16,33	6,51	NA	3,12	1,92	5,05	0,0000	0,7228
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	Thrombocytopenia	142	24	16,90	118	83,10	NA	NA	NA	-	-	-	-	0,7228
Patients with at least one AE	total	-	SVd Arm	Nervous system disorders	Dizziness	195	24	12,31	171	87,69	NA	NA	NA	2,54	1,21	5,31	0,0106	NA
Patients with at least one AE	total	-	Vd Arm	Nervous system disorders	Dizziness	204	10	4,90	194	95,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Infections and infestations	Upper respiratory tract infection	80	17	21,25	63	78,75	NA	17,45	NA	2,46	0,96	6,31	0,0532	0,0469
Patients with at least one AE	Gender	Female	Vd Arm	Infections and infestations	Upper respiratory tract infection	91	8	8,79	83	91,21	NA	NA	NA	-	-	-	-	0,0469
Patients with at least one AE	Gender	Male	SVd Arm	Infections and infestations	Upper respiratory tract infection	115	13	11,30	102	88,70	NA	NA	NA	0,74	0,36	1,53	0,4117	0,0469
Patients with at least one AE	Gender	Male	Vd Arm	Infections and infestations	Upper respiratory tract infection	113	17	15,04	96	84,96	NA	NA	NA	-	-	-	-	0,0469
Patients with at least one AE	Age Group	<65	SVd Arm	Infections and infestations	Upper respiratory tract infection	86	12	13,95	74	86,05	NA	NA	NA	0,88	0,37	2,07	0,7650	0,3543
Patients with at least one AE	Age Group	<65	Vd Arm	Infections and infestations	Upper respiratory tract infection	75	12	16,00	63	84,00	NA	NA	NA	-	-	-	-	0,3543
Patients with at least one AE	Age Group	>=65	SVd Arm	Infections and infestations	Upper respiratory tract infection	109	18	16,51	91	83,49	NA	17,45	NA	1,49	0,72	3,06	0,2752	0,3543
Patients with at least one AE	Age Group	>=65	Vd Arm	Infections and infestations	Upper respiratory tract infection	129	13	10,08	116	89,92	NA	NA	NA	-	-	-	-	0,3543
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Upper respiratory tract infection	173	30	17,34	143	82,66	NA	NA	NA	1,23	0,70	2,15	0,4716	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Upper respiratory tract infection	174	23	13,22	151	86,78	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Upper respiratory tract infection	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Upper respiratory tract infection	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Upper respiratory tract infection	163	27	16,56	136	83,44	NA	NA	NA	1,30	0,71	2,36	0,3887	0,5895
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Upper respiratory tract infection	173	20	11,56	153	88,44	NA	NA	NA	-	-	-	-	0,5895
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Upper respiratory tract infection	32	3	9,38	29	90,62	NA	NA	NA	0,81	0,17	3,98	0,8003	0,5895
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Upper respiratory tract infection	31	5	16,13	26	83,87	NA	15,44	NA	-	-	-	-	0,5895
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Upper respiratory tract infection	18	4	22,22	14	77,78	NA	21,42	NA	0,44	0,04	5,22	0,5076	0,3452
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Upper respiratory tract infection	17	3	17,65	14	82,35	11,66	11,66	NA	-	-	-	-	0,3452
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Upper respiratory tract infection	61	8	13,11	53	86,89	NA	NA	NA	1,09	0,38	3,13	0,8787	0,3452
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Upper respiratory tract infection	64	7	10,94	57	89,06	NA	NA	NA	-	-	-	-	0,3452
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Upper respiratory tract infection	47	11	23,40	36	76,60	NA	17,45	NA	0,71	0,29	1,74	0,4594	0,3452
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Upper respiratory tract infection	53	13	24,53	40	75,47	24,34	11,04	NA	-	-	-	-	0,3452
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Upper respiratory tract infection	69	7	10,14	62	89,86	NA	NA	NA	3,51	0,70	17,65	0,1067	0,3452
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Upper respiratory tract infection	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,3452
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Upper respiratory tract infection	117	23	19,66	94	80,34	NA	25,30	NA	1,12	0,61	2,07	0,7199	0,8259
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Upper respiratory tract infection	136	21	15,44	115	84,56	NA	NA	NA	-	-	-	-	0,8259
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Upper respiratory tract infection	78	7	8,97	71	91,03	NA	NA	NA	1,31	0,37	4,63	0,6746	0,8259
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Upper respiratory tract infection	68	4	5,88	64	94,12	NA	NA	NA	-	-	-	-	0,8259
Patients with at least one AE	Race	Races other than White	SVd Arm	Infections and infestations	Upper respiratory tract infection	34	2	5,88	32	94,12	NA	NA	NA	0,70	0,11	4,32	0,6975	0,5586
Patients with at least one AE	Race	Races other than White	Vd Arm	Infections and infestations	Upper respiratory tract infection	42	4	9,52	38	90,48	NA	NA	NA	-	-	-	-	0,5586
Patients with at least one AE	Race	White	SVd Arm	Infections and infestations	Upper respiratory tract infection	161	28	17,39	133	82,61	NA	NA	NA	1,23	0,69	2,20	0,4746	0,5586
Patients with at least one AE	Race	White	Vd Arm	Infections and infestations	Upper respiratory tract infection	162	21	12,96	141	87,04	NA	NA	NA	-	-	-	-	0,5586

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Upper respiratory tract infection	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Upper respiratory tract infection	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Upper respiratory tract infection	171	25	14,62	146	85,38	NA	NA	NA	1,04	0,59	1,84	0,8866	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Upper respiratory tract infection	185	25	13,51	160	86,49	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Infections and infestations	Upper respiratory tract infection	48	9	18,75	39	81,25	NA	NA	NA	0,98	0,35	2,71	0,9658	0,6270
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Infections and infestations	Upper respiratory tract infection	47	7	14,89	40	85,11	NA	NA	NA	-	-	-	-	0,6270
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Infections and infestations	Upper respiratory tract infection	147	21	14,29	126	85,71	NA	NA	NA	1,32	0,70	2,50	0,3964	0,6270
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Infections and infestations	Upper respiratory tract infection	157	18	11,46	139	88,54	NA	NA	NA	-	-	-	-	0,6270
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Upper respiratory tract infection	98	17	17,35	81	82,65	NA	25,30	NA	1,73	0,82	3,67	0,1484	0,1724
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Upper respiratory tract infection	104	12	11,54	92	88,46	NA	NA	NA	-	-	-	-	0,1724
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Upper respiratory tract infection	97	13	13,40	84	86,60	NA	NA	NA	0,81	0,37	1,78	0,6007	0,1724
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Upper respiratory tract infection	100	13	13,00	87	87,00	NA	NA	NA	-	-	-	-	0,1724
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Upper respiratory tract infection	98	14	14,29	84	85,71	NA	NA	NA	0,90	0,41	1,96	0,7852	0,3277
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Upper respiratory tract infection	111	16	14,41	95	85,59	NA	NA	NA	-	-	-	-	0,3277
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Upper respiratory tract infection	97	16	16,49	81	83,51	NA	25,30	NA	1,60	0,68	3,75	0,2765	0,3277
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Upper respiratory tract infection	93	9	9,68	84	90,32	NA	NA	NA	-	-	-	-	0,3277
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Upper respiratory tract infection	61	12	19,67	49	80,33	NA	18,79	NA	0,94	0,38	2,34	0,8933	0,5556
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Upper respiratory tract infection	62	9	14,52	53	85,48	NA	NA	NA	-	-	-	-	0,5556

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Upper respiratory tract infection	134	18	13,43	116	86,57	NA	NA	NA	1,33	0,66	2,66	0,4236	0,5556
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Upper respiratory tract infection	142	16	11,27	126	88,73	NA	NA	NA	-	-	-	-	0,5556
Patients with at least one AE	total	-	SVd Arm	Nervous system disorders	Dysgeusia	195	13	6,67	182	93,33	NA	NA	NA	13,87	1,81	106,11	0,0009	NA
Patients with at least one AE	total	-	Vd Arm	Nervous system disorders	Dysgeusia	204	1	0,49	203	99,51	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Infections and infestations	Urinary tract infection	80	10	12,50	70	87,50	NA	NA	NA	1,58	0,55	4,57	0,3908	0,9580
Patients with at least one AE	Gender	Female	Vd Arm	Infections and infestations	Urinary tract infection	91	7	7,69	84	92,31	NA	NA	NA	-	-	-	-	0,9580
Patients with at least one AE	Gender	Male	SVd Arm	Infections and infestations	Urinary tract infection	115	4	3,48	111	96,52	NA	42,74	NA	1,50	0,25	9,04	0,6571	0,9580
Patients with at least one AE	Gender	Male	Vd Arm	Infections and infestations	Urinary tract infection	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,9580
Patients with at least one AE	Age Group	<65	SVd Arm	Infections and infestations	Urinary tract infection	86	6	6,98	80	93,02	42,74	42,74	NA	1,27	0,29	5,51	0,7478	0,7356
Patients with at least one AE	Age Group	<65	Vd Arm	Infections and infestations	Urinary tract infection	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,7356
Patients with at least one AE	Age Group	>=65	SVd Arm	Infections and infestations	Urinary tract infection	109	8	7,34	101	92,66	NA	NA	NA	1,74	0,60	5,06	0,3049	0,7356
Patients with at least one AE	Age Group	>=65	Vd Arm	Infections and infestations	Urinary tract infection	129	6	4,65	123	95,35	NA	NA	NA	-	-	-	-	0,7356
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	Urinary tract infection	173	13	7,51	160	92,49	NA	NA	NA	2,10	0,79	5,56	0,1289	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	Urinary tract infection	174	6	3,45	168	96,55	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	Urinary tract infection	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	Urinary tract infection	16	3	18,75	13	81,25	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	Urinary tract infection	163	13	7,98	150	92,02	NA	NA	NA	2,12	0,80	5,63	0,1231	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	Urinary tract infection	173	6	3,47	167	96,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	Urinary tract infection	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	Urinary tract infection	31	3	9,68	28	90,32	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	Urinary tract infection	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,6300
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	Urinary tract infection	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,6300
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	Urinary tract infection	61	5	8,20	56	91,80	NA	NA	NA	1,42	0,32	6,34	0,6477	0,6300

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	Urinary tract infection	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,6300
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	Urinary tract infection	47	7	14,89	40	85,11	NA	NA	NA	2,34	0,58	9,36	0,2176	0,6300
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	Urinary tract infection	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,6300
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	Urinary tract infection	69	1	1,45	68	98,55	-	-	-	-	-	-	-	0,6300
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	Urinary tract infection	70	2	2,86	68	97,14	-	-	-	-	-	-	-	0,6300
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	Urinary tract infection	117	13	11,11	104	88,89	NA	NA	NA	2,49	0,93	6,63	0,0601	NA
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	Urinary tract infection	136	6	4,41	130	95,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	Urinary tract infection	78	1	1,28	77	98,72	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	Urinary tract infection	68	3	4,41	65	95,59	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	SVd Arm	Infections and infestations	Urinary tract infection	34	1	2,94	33	97,06	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Infections and infestations	Urinary tract infection	42	1	2,38	41	97,62	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Infections and infestations	Urinary tract infection	161	13	8,07	148	91,93	NA	NA	NA	1,68	0,68	4,12	0,2529	NA
Patients with at least one AE	Race	White	Vd Arm	Infections and infestations	Urinary tract infection	162	8	4,94	154	95,06	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	Urinary tract infection	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	Urinary tract infection	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	Urinary tract infection	171	11	6,43	160	93,57	NA	42,74	NA	1,40	0,54	3,60	0,4849	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	Urinary tract infection	185	8	4,32	177	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Infections and infestations	Urinary tract infection	48	4	8,33	44	91,67	NA	NA	NA	4,19	0,45	38,91	0,1749	0,2999
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Infections and infestations	Urinary tract infection	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,2999

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Infections and infestations	Urinary tract infection	147	10	6,80	137	93,20	NA	42,74	NA	1,16	0,45	3,02	0,7590	0,2999
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Infections and infestations	Urinary tract infection	157	8	5,10	149	94,90	NA	NA	NA	-	-	-	-	0,2999
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	Urinary tract infection	98	5	5,10	93	94,90	NA	NA	NA	1,06	0,31	3,68	0,9247	0,4731
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	Urinary tract infection	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,4731
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	Urinary tract infection	97	9	9,28	88	90,72	NA	42,74	NA	2,01	0,60	6,75	0,2523	0,4731
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	Urinary tract infection	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,4731
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	Urinary tract infection	98	7	7,14	91	92,86	NA	42,74	NA	0,81	0,28	2,35	0,6994	0,1033
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	Urinary tract infection	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,1033
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	Urinary tract infection	97	7	7,22	90	92,78	NA	NA	NA	5,74	0,70	46,83	0,0652	0,1033
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	Urinary tract infection	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,1033
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	Urinary tract infection	61	5	8,20	56	91,80	NA	NA	NA	5,39	0,61	47,41	0,0912	0,1738
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	Urinary tract infection	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,1738
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	Urinary tract infection	134	9	6,72	125	93,28	NA	42,74	NA	1,03	0,38	2,76	0,9539	0,1738
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	Urinary tract infection	142	8	5,63	134	94,37	NA	NA	NA	-	-	-	-	0,1738
Patients with at least one AE	total	-	SVd Arm	Nervous system disorders	Headache	195	20	10,26	175	89,74	NA	NA	NA	1,70	0,84	3,43	0,1329	NA
Patients with at least one AE	total	-	Vd Arm	Nervous system disorders	Headache	204	13	6,37	191	93,63	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Eye disorders	Vision blurred	80	4	5,00	76	95,00	NA	NA	NA	1,06	0,26	4,27	0,9305	0,4760
Patients with at least one AE	Gender	Female	Vd Arm	Eye disorders	Vision blurred	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,4760
Patients with at least one AE	Gender	Male	SVd Arm	Eye disorders	Vision blurred	115	9	7,83	106	92,17	NA	NA	NA	2,03	0,67	6,21	0,2035	0,4760
Patients with at least one AE	Gender	Male	Vd Arm	Eye disorders	Vision blurred	113	5	4,42	108	95,58	NA	NA	NA	-	-	-	-	0,4760
Patients with at least one AE	Age Group	<65	SVd Arm	Eye disorders	Vision blurred	86	5	5,81	81	94,19	NA	NA	NA	0,43	0,13	1,36	0,1398	0,0108
Patients with at least one AE	Age Group	<65	Vd Arm	Eye disorders	Vision blurred	75	7	9,33	68	90,67	NA	NA	NA	-	-	-	-	0,0108
Patients with at least one AE	Age Group	>=65	SVd Arm	Eye disorders	Vision blurred	109	8	7,34	101	92,66	NA	NA	NA	5,40	1,13	25,87	0,0189	0,0108
Patients with at least one AE	Age Group	>=65	Vd Arm	Eye disorders	Vision blurred	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	0,0108

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Eye disorders	Vision blurred	173	13	7,51	160	92,49	NA	NA	NA	2,27	0,86	5,99	0,0880	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Eye disorders	Vision blurred	174	6	3,45	168	96,55	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Eye disorders	Vision blurred	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Eye disorders	Vision blurred	16	2	12,50	14	87,50	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Eye disorders	Vision blurred	163	12	7,36	151	92,64	NA	NA	NA	2,19	0,82	5,85	0,1078	0,2342
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Eye disorders	Vision blurred	173	6	3,47	167	96,53	NA	NA	NA	-	-	-	-	0,2342
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Eye disorders	Vision blurred	32	1	3,12	31	96,88	NA	NA	NA	0,45	0,04	5,02	0,5079	0,2342
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Eye disorders	Vision blurred	31	3	9,68	28	90,32	NA	19,12	NA	-	-	-	-	0,2342
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Eye disorders	Vision blurred	18	3	16,67	15	83,33	NA	NA	NA	1,53	0,14	16,90	0,7273	0,5555
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Eye disorders	Vision blurred	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,5555
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Eye disorders	Vision blurred	61	9	14,75	52	85,25	NA	NA	NA	3,48	0,94	12,87	0,0463	0,5555
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Eye disorders	Vision blurred	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,5555
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Eye disorders	Vision blurred	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,5555
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Eye disorders	Vision blurred	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,5555
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Eye disorders	Vision blurred	69	0	0,00	69	100,00	-	-	-	-	-	-	-	0,5555
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Eye disorders	Vision blurred	70	5	7,14	65	92,86	-	-	-	-	-	-	-	0,5555
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Eye disorders	Vision blurred	117	12	10,26	105	89,74	NA	NA	NA	3,44	1,11	10,70	0,0233	0,0326
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Eye disorders	Vision blurred	136	4	2,94	132	97,06	NA	NA	NA	-	-	-	-	0,0326
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Eye disorders	Vision blurred	78	1	1,28	77	98,72	NA	NA	NA	0,24	0,03	2,09	0,1606	0,0326
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Eye disorders	Vision blurred	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,0326
Patients with at least one AE	Race	Races other than White	SVd Arm	Eye disorders	Vision blurred	34	1	2,94	33	97,06	NA	NA	NA	0,64	0,06	6,40	0,6987	0,3104
Patients with at least one AE	Race	Races other than White	Vd Arm	Eye disorders	Vision blurred	42	4	9,52	38	90,48	NA	NA	NA	-	-	-	-	0,3104
Patients with at least one AE	Race	White	SVd Arm	Eye disorders	Vision blurred	161	12	7,45	149	92,55	NA	NA	NA	2,36	0,83	6,73	0,0973	0,3104
Patients with at least one AE	Race	White	Vd Arm	Eye disorders	Vision blurred	162	5	3,09	157	96,91	NA	NA	NA	-	-	-	-	0,3104
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Eye disorders	Vision blurred	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Eye disorders	Vision blurred	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Eye disorders	Vision blurred	171	12	7,02	159	92,98	NA	NA	NA	1,50	0,63	3,59	0,3544	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Eye disorders	Vision blurred	185	9	4,86	176	95,14	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Eye disorders	Vision blurred	48	1	2,08	47	97,92	NA	NA	NA	0,50	0,05	5,56	0,5673	0,3113
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Eye disorders	Vision blurred	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,3113
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Eye disorders	Vision blurred	147	12	8,16	135	91,84	NA	NA	NA	1,90	0,75	4,86	0,1702	0,3113
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Eye disorders	Vision blurred	157	7	4,46	150	95,54	NA	NA	NA	-	-	-	-	0,3113
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Eye disorders	Vision blurred	98	5	5,10	93	94,90	NA	NA	NA	1,06	0,31	3,68	0,9243	0,3948
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Eye disorders	Vision blurred	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,3948
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Eye disorders	Vision blurred	97	8	8,25	89	91,75	NA	NA	NA	2,25	0,67	7,53	0,1758	0,3948
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Eye disorders	Vision blurred	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,3948
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Eye disorders	Vision blurred	98	2	2,04	96	97,96	NA	NA	NA	0,40	0,08	2,03	0,2551	0,0339
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Eye disorders	Vision blurred	111	6	5,41	105	94,59	NA	NA	NA	-	-	-	-	0,0339
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Eye disorders	Vision blurred	97	11	11,34	86	88,66	NA	NA	NA	3,76	1,04	13,53	0,0299	0,0339
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Eye disorders	Vision blurred	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,0339
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Eye disorders	Vision blurred	61	2	3,28	59	96,72	NA	NA	NA	1,13	0,16	8,11	0,9034	0,7104
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Eye disorders	Vision blurred	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,7104
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Eye disorders	Vision blurred	134	11	8,21	123	91,79	NA	NA	NA	1,71	0,66	4,44	0,2645	0,7104
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Eye disorders	Vision blurred	142	7	4,93	135	95,07	NA	NA	NA	-	-	-	-	0,7104

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	total	-	SVd Arm	Nervous system disorders	Neuropathy peripheral	195	38	19,49	157	80,51	NA	NA	NA	0,54	0,36	0,82	0,0031	NA
Patients with at least one AE	total	-	Vd Arm	Nervous system disorders	Neuropathy peripheral	204	61	29,90	143	70,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Eye disorders	Visual impairment	80	5	6,25	75	93,75	NA	NA	NA	2,61	0,29	23,95	0,3785	0,9639
Patients with at least one AE	Gender	Female	Vd Arm	Eye disorders	Visual impairment	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,9639
Patients with at least one AE	Gender	Male	SVd Arm	Eye disorders	Visual impairment	115	9	7,83	106	92,17	NA	NA	NA	2,77	0,74	10,39	0,1152	0,9639
Patients with at least one AE	Gender	Male	Vd Arm	Eye disorders	Visual impairment	113	3	2,65	110	97,35	NA	NA	NA	-	-	-	-	0,9639
Patients with at least one AE	Age Group	<65	SVd Arm	Eye disorders	Visual impairment	86	6	6,98	80	93,02	NA	NA	NA	1,87	0,35	10,07	0,4618	0,4313
Patients with at least one AE	Age Group	<65	Vd Arm	Eye disorders	Visual impairment	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,4313
Patients with at least one AE	Age Group	>=65	SVd Arm	Eye disorders	Visual impairment	109	8	7,34	101	92,66	NA	NA	NA	4,69	0,99	22,30	0,0327	0,4313
Patients with at least one AE	Age Group	>=65	Vd Arm	Eye disorders	Visual impairment	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	0,4313
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Eye disorders	Visual impairment	173	12	6,94	161	93,06	NA	NA	NA	3,64	1,01	13,15	0,0357	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Eye disorders	Visual impairment	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Eye disorders	Visual impairment	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Eye disorders	Visual impairment	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Eye disorders	Visual impairment	163	13	7,98	150	92,02	NA	NA	NA	3,01	0,95	9,51	0,0496	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Eye disorders	Visual impairment	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Eye disorders	Visual impairment	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Eye disorders	Visual impairment	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Eye disorders	Visual impairment	18	2	11,11	16	88,89	30,03	24,48	NA	0,87	0,05	15,38	0,9219	0,9909
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Eye disorders	Visual impairment	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,9909
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Eye disorders	Visual impairment	61	3	4,92	58	95,08	NA	NA	NA	0,85	0,17	4,26	0,8427	0,9909
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Eye disorders	Visual impairment	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,9909
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Eye disorders	Visual impairment	47	4	8,51	43	91,49	-	-	-	-	-	-	-	0,9909
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Eye disorders	Visual impairment	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,9909
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Eye disorders	Visual impairment	69	5	7,25	64	92,75	-	-	-	-	-	-	-	0,9909
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Eye disorders	Visual impairment	70	0	0,00	70	100,00	-	-	-	-	-	-	-	0,9909
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Eye disorders	Visual impairment	117	8	6,84	109	93,16	NA	NA	NA	2,39	0,63	9,09	0,1896	0,4822
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Eye disorders	Visual impairment	136	3	2,21	133	97,79	NA	NA	NA	-	-	-	-	0,4822
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Eye disorders	Visual impairment	78	6	7,69	72	92,31	NA	NA	NA	5,89	0,70	49,90	0,0669	0,4822

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Eye disorders	Visual impairment	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,4822
Patients with at least one AE	Race	Races other than White	SVd Arm	Eye disorders	Visual impairment	34	2	5,88	32	94,12	NA	NA	NA	3,46	0,30	39,50	0,2899	0,9723
Patients with at least one AE	Race	Races other than White	Vd Arm	Eye disorders	Visual impairment	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,9723
Patients with at least one AE	Race	White	SVd Arm	Eye disorders	Visual impairment	161	12	7,45	149	92,55	NA	NA	NA	3,30	0,92	11,81	0,0530	0,9723
Patients with at least one AE	Race	White	Vd Arm	Eye disorders	Visual impairment	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	0,9723
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Eye disorders	Visual impairment	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Eye disorders	Visual impairment	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Eye disorders	Visual impairment	171	13	7,60	158	92,40	NA	NA	NA	5,09	1,41	18,39	0,0063	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Eye disorders	Visual impairment	185	3	1,62	182	98,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Eye disorders	Visual impairment	48	5	10,42	43	89,58	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Eye disorders	Visual impairment	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Eye disorders	Visual impairment	147	9	6,12	138	93,88	NA	NA	NA	2,26	0,69	7,47	0,1682	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Eye disorders	Visual impairment	157	4	2,55	153	97,45	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Eye disorders	Visual impairment	98	4	4,08	94	95,92	NA	NA	NA	1,43	0,31	6,53	0,6448	0,1426
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Eye disorders	Visual impairment	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,1426
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Eye disorders	Visual impairment	97	10	10,31	87	89,69	NA	NA	NA	9,74	1,23	77,02	0,0087	0,1426
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Eye disorders	Visual impairment	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,1426
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Eye disorders	Visual impairment	98	9	9,18	89	90,82	NA	NA	NA	5,08	1,07	24,03	0,0239	0,3976
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Eye disorders	Visual impairment	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,3976
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Eye disorders	Visual impairment	97	5	5,15	92	94,85	NA	NA	NA	1,91	0,37	9,91	0,4324	0,3976

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Eye disorders	Visual impairment	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,3976
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Eye disorders	Visual impairment	61	5	8,20	56	91,80	NA	NA	NA	5,24	0,60	46,01	0,0977	0,7145
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Eye disorders	Visual impairment	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,7145
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Eye disorders	Visual impairment	134	9	6,72	125	93,28	NA	NA	NA	3,25	0,84	12,58	0,0729	0,7145
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Eye disorders	Visual impairment	142	3	2,11	139	97,89	NA	NA	NA	-	-	-	-	0,7145
Patients with at least one AE	total	-	SVd Arm	Nervous system disorders	Paraesthesia	195	5	2,56	190	97,44	NA	NA	NA	0,33	0,12	0,90	0,0237	NA
Patients with at least one AE	total	-	Vd Arm	Nervous system disorders	Paraesthesia	204	16	7,84	188	92,16	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Gastrointestinal disorders	Vomiting	80	25	31,25	55	68,75	NA	NA	NA	7,96	2,74	23,07	0,0000	0,0694
Patients with at least one AE	Gender	Female	Vd Arm	Gastrointestinal disorders	Vomiting	91	4	4,40	87	95,60	NA	NA	NA	-	-	-	-	0,0694
Patients with at least one AE	Gender	Male	SVd Arm	Gastrointestinal disorders	Vomiting	115	15	13,04	100	86,96	NA	NA	NA	2,11	0,80	5,51	0,1215	0,0694
Patients with at least one AE	Gender	Male	Vd Arm	Gastrointestinal disorders	Vomiting	113	6	5,31	107	94,69	NA	NA	NA	-	-	-	-	0,0694
Patients with at least one AE	Age Group	<65	SVd Arm	Gastrointestinal disorders	Vomiting	86	20	23,26	66	76,74	NA	NA	NA	6,93	2,03	23,64	0,0004	0,3573
Patients with at least one AE	Age Group	<65	Vd Arm	Gastrointestinal disorders	Vomiting	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,3573
Patients with at least one AE	Age Group	>=65	SVd Arm	Gastrointestinal disorders	Vomiting	109	20	18,35	89	81,65	NA	NA	NA	3,42	1,44	8,14	0,0032	0,3573
Patients with at least one AE	Age Group	>=65	Vd Arm	Gastrointestinal disorders	Vomiting	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	0,3573
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Vomiting	173	38	21,97	135	78,03	NA	NA	NA	5,09	2,36	10,96	0,0000	0,0940
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Vomiting	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	0,0940
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Vomiting	12	1	8,33	11	91,67	NA	NA	NA	0,54	0,04	6,64	0,6287	0,0940
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Vomiting	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,0940
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	Vomiting	163	36	22,09	127	77,91	NA	NA	NA	4,61	2,22	9,58	0,0000	0,8334
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	Vomiting	173	9	5,20	164	94,80	NA	NA	NA	-	-	-	-	0,8334
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	Vomiting	32	4	12,50	28	87,50	NA	NA	NA	3,56	0,36	35,22	0,2486	0,8334

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	Vomiting	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,8334
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	Vomiting	18	3	16,67	15	83,33	NA	NA	NA	1,35	0,22	8,41	0,7447	0,4007
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	Vomiting	17	2	11,76	15	88,24	NA	NA	NA	-	-	-	-	0,4007
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	Vomiting	61	16	26,23	45	73,77	NA	9,26	NA	6,21	1,79	21,53	0,0011	0,4007
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	Vomiting	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,4007
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	Vomiting	47	4	8,51	43	91,49	-	-	-	-	-	-	-	0,4007
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	Vomiting	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,4007
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	Vomiting	69	17	24,64	52	75,36	NA	NA	NA	3,76	1,36	10,39	0,0062	0,4007
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	Vomiting	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,4007
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	Vomiting	117	20	17,09	97	82,91	NA	NA	NA	4,83	1,80	12,99	0,0006	0,7071
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	Vomiting	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,7071
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	Vomiting	78	20	25,64	58	74,36	NA	13,11	NA	3,69	1,37	9,99	0,0059	0,7071
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	Vomiting	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,7071
Patients with at least one AE	Race	Races other than White	SVd Arm	Gastrointestinal disorders	Vomiting	34	13	38,24	21	61,76	NA	13,11	NA	2,86	1,04	7,86	0,0348	0,1214
Patients with at least one AE	Race	Races other than White	Vd Arm	Gastrointestinal disorders	Vomiting	42	7	16,67	35	83,33	NA	NA	NA	-	-	-	-	0,1214
Patients with at least one AE	Race	White	SVd Arm	Gastrointestinal disorders	Vomiting	161	27	16,77	134	83,23	NA	NA	NA	9,93	2,97	33,22	0,0000	0,1214
Patients with at least one AE	Race	White	Vd Arm	Gastrointestinal disorders	Vomiting	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	0,1214
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Vomiting	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Vomiting	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	Vomiting	171	33	19,30	138	80,70	NA	NA	NA	4,73	2,17	10,32	0,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	Vomiting	185	8	4,32	177	95,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	Vomiting	48	13	27,08	35	72,92	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	Vomiting	47	0	0,00	47	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	Vomiting	147	27	18,37	120	81,63	NA	NA	NA	3,05	1,47	6,31	0,0016	NA
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	Vomiting	157	10	6,37	147	93,63	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	Vomiting	98	24	24,49	74	75,51	NA	NA	NA	4,35	1,77	10,70	0,0005	0,8715
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	Vomiting	104	6	5,77	98	94,23	NA	NA	NA	-	-	-	-	0,8715
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	Vomiting	97	16	16,49	81	83,51	NA	NA	NA	4,90	1,61	14,88	0,0020	0,8715
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	Vomiting	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,8715
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	Vomiting	98	21	21,43	77	78,57	NA	NA	NA	4,58	1,83	11,51	0,0004	0,9404
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	Vomiting	111	6	5,41	105	94,59	NA	NA	NA	-	-	-	-	0,9404
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	Vomiting	97	19	19,59	78	80,41	NA	NA	NA	4,34	1,47	12,80	0,0037	0,9404
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	Vomiting	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,9404
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	Vomiting	61	15	24,59	46	75,41	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	Vomiting	62	0	0,00	62	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	Vomiting	134	25	18,66	109	81,34	NA	NA	NA	2,90	1,39	6,05	0,0030	NA
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	Vomiting	142	10	7,04	132	92,96	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Nervous system disorders	Peripheral sensory neuropathy	195	19	9,74	176	90,26	NA	NA	NA	0,77	0,42	1,39	0,3759	NA
Patients with at least one AE	total	-	Vd Arm	Nervous system disorders	Peripheral sensory neuropathy	204	26	12,75	178	87,25	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Investigations	Weight decreased	80	24	30,00	56	70,00	NA	NA	NA	6,12	2,45	15,28	0,0000	0,0111

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Female	Vd Arm	Investigations	Weight decreased	91	6	6,59	85	93,41	NA	NA	NA	-	-	-	-	0,0111
Patients with at least one AE	Gender	Male	SVd Arm	Investigations	Weight decreased	115	27	23,48	88	76,52	NA	NA	NA	1,49	0,82	2,69	0,1891	0,0111
Patients with at least one AE	Gender	Male	Vd Arm	Investigations	Weight decreased	113	19	16,81	94	83,19	NA	NA	NA	-	-	-	-	0,0111
Patients with at least one AE	Age Group	<65	SVd Arm	Investigations	Weight decreased	86	21	24,42	65	75,58	NA	NA	NA	2,08	0,93	4,65	0,0687	0,5751
Patients with at least one AE	Age Group	<65	Vd Arm	Investigations	Weight decreased	75	9	12,00	66	88,00	NA	NA	NA	-	-	-	-	0,5751
Patients with at least one AE	Age Group	>=65	SVd Arm	Investigations	Weight decreased	109	30	27,52	79	72,48	NA	NA	NA	2,78	1,50	5,15	0,0007	0,5751
Patients with at least one AE	Age Group	>=65	Vd Arm	Investigations	Weight decreased	129	16	12,40	113	87,60	NA	NA	NA	-	-	-	-	0,5751
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Investigations	Weight decreased	173	42	24,28	131	75,72	NA	NA	NA	2,62	1,50	4,57	0,0004	0,8950
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Investigations	Weight decreased	174	18	10,34	156	89,66	NA	NA	NA	-	-	-	-	0,8950
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Investigations	Weight decreased	12	7	58,33	5	41,67	3,02	1,64	NA	2,91	0,70	12,05	0,1282	0,8950
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Investigations	Weight decreased	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,8950
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Investigations	Weight decreased	163	39	23,93	124	76,07	NA	NA	NA	2,32	1,35	3,99	0,0017	0,6554
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Investigations	Weight decreased	173	20	11,56	153	88,44	NA	NA	NA	-	-	-	-	0,6554
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Investigations	Weight decreased	32	12	37,50	20	62,50	8,28	3,02	NA	3,06	1,04	9,02	0,0347	0,6554
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Investigations	Weight decreased	31	5	16,13	26	83,87	NA	NA	NA	-	-	-	-	0,6554
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Investigations	Weight decreased	18	4	22,22	14	77,78	NA	NA	NA	3,32	0,37	30,05	0,2580	0,9800
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Investigations	Weight decreased	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,9800
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Investigations	Weight decreased	61	13	21,31	48	78,69	NA	NA	NA	2,35	0,89	6,22	0,0759	0,9800
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Investigations	Weight decreased	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,9800
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Investigations	Weight decreased	47	9	19,15	38	80,85	NA	NA	NA	2,12	0,65	6,97	0,2036	0,9800
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Investigations	Weight decreased	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,9800
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Investigations	Weight decreased	69	25	36,23	44	63,77	NA	5,78	NA	2,66	1,36	5,19	0,0029	0,9800
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Investigations	Weight decreased	70	14	20,00	56	80,00	NA	NA	NA	-	-	-	-	0,9800
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Investigations	Weight decreased	117	24	20,51	93	79,49	NA	NA	NA	2,58	1,25	5,30	0,0076	0,9891
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Investigations	Weight decreased	136	11	8,09	125	91,91	NA	NA	NA	-	-	-	-	0,9891
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Investigations	Weight decreased	78	27	34,62	51	65,38	NA	8,28	NA	2,56	1,32	4,98	0,0043	0,9891
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Investigations	Weight decreased	68	14	20,59	54	79,41	NA	NA	NA	-	-	-	-	0,9891
Patients with at least one AE	Race	Races other than White	SVd Arm	Investigations	Weight decreased	34	14	41,18	20	58,82	8,28	4,04	NA	2,91	1,15	7,36	0,0184	0,8514
Patients with at least one AE	Race	Races other than White	Vd Arm	Investigations	Weight decreased	42	9	21,43	33	78,57	NA	NA	NA	-	-	-	-	0,8514

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	SVd Arm	Investigations	Weight decreased	161	37	22,98	124	77,02	NA	NA	NA	2,62	1,44	4,77	0,0011	0,8514
Patients with at least one AE	Race	White	Vd Arm	Investigations	Weight decreased	162	16	9,88	146	90,12	NA	NA	NA	-	-	-	-	0,8514
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Investigations	Weight decreased	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Investigations	Weight decreased	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Investigations	Weight decreased	171	42	24,56	129	75,44	NA	NA	NA	2,33	1,39	3,90	0,0010	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Investigations	Weight decreased	185	23	12,43	162	87,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Investigations	Weight decreased	48	10	20,83	38	79,17	NA	NA	NA	2,33	0,79	6,86	0,1156	0,8733
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Investigations	Weight decreased	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,8733
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Investigations	Weight decreased	147	41	27,89	106	72,11	NA	NA	NA	2,57	1,50	4,41	0,0004	0,8733
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Investigations	Weight decreased	157	20	12,74	137	87,26	NA	NA	NA	-	-	-	-	0,8733
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Investigations	Weight decreased	98	27	27,55	71	72,45	NA	NA	NA	2,74	1,40	5,36	0,0023	0,7208
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Investigations	Weight decreased	104	13	12,50	91	87,50	NA	NA	NA	-	-	-	-	0,7208
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Investigations	Weight decreased	97	24	24,74	73	75,26	NA	NA	NA	2,30	1,14	4,60	0,0161	0,7208
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Investigations	Weight decreased	100	12	12,00	88	88,00	NA	NA	NA	-	-	-	-	0,7208
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Investigations	Weight decreased	98	26	26,53	72	73,47	NA	NA	NA	2,44	1,29	4,61	0,0047	0,8655
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Investigations	Weight decreased	111	16	14,41	95	85,59	NA	NA	NA	-	-	-	-	0,8655
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Investigations	Weight decreased	97	25	25,77	72	74,23	NA	NA	NA	2,66	1,24	5,70	0,0091	0,8655
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Investigations	Weight decreased	93	9	9,68	84	90,32	NA	NA	NA	-	-	-	-	0,8655
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Investigations	Weight decreased	61	13	21,31	48	78,69	NA	NA	NA	1,47	0,60	3,57	0,3933	0,1707

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Investigations	Weight decreased	62	9	14,52	53	85,48	NA	NA	NA	-	-	-	-	0,1707
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Investigations	Weight decreased	134	38	28,36	96	71,64	NA	NA	NA	3,10	1,71	5,60	0,0001	0,1707
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Investigations	Weight decreased	142	16	11,27	126	88,73	NA	NA	NA	-	-	-	-	0,1707
Patients with at least one AE	total	-	SVd Arm	Nervous system disorders	Polyneuropathy	195	12	6,15	183	93,85	NA	NA	NA	0,91	0,41	1,99	0,8073	NA
Patients with at least one AE	total	-	Vd Arm	Nervous system disorders	Polyneuropathy	204	14	6,86	190	93,14	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Blood and lymphatic system disorders	-	80	49	61,25	31	38,75	2,83	1,38	NA	2,17	1,36	3,47	0,0009	0,5044
Patients with at least one AE	Gender	Female	Vd Arm	Blood and lymphatic system disorders	-	91	36	39,56	55	60,44	19,91	12,45	NA	-	-	-	-	0,5044
Patients with at least one AE	Gender	Male	SVd Arm	Blood and lymphatic system disorders	-	115	82	71,30	33	28,70	1,41	1,41	3,98	2,67	1,82	3,92	0,0000	0,5044
Patients with at least one AE	Gender	Male	Vd Arm	Blood and lymphatic system disorders	-	113	41	36,28	72	63,72	NA	18,46	NA	-	-	-	-	0,5044
Patients with at least one AE	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	-	86	61	70,93	25	29,07	2,10	1,41	4,27	2,51	1,59	3,96	0,0000	0,7398
Patients with at least one AE	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	-	75	28	37,33	47	62,67	NA	12,45	NA	-	-	-	-	0,7398
Patients with at least one AE	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	-	109	70	64,22	39	35,78	1,41	0,82	4,17	2,27	1,56	3,30	0,0000	0,7398
Patients with at least one AE	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	-	129	49	37,98	80	62,02	20,47	18,46	NA	-	-	-	-	0,7398
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	-	173	116	67,05	57	32,95	1,64	1,41	4,14	2,49	1,82	3,40	0,0000	0,2338
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	-	174	63	36,21	111	63,79	NA	18,46	NA	-	-	-	-	0,2338
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	-	12	10	83,33	2	16,67	1,41	0,69	NA	1,22	0,39	3,78	0,7337	0,2338
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	-	16	9	56,25	7	43,75	2,10	0,69	NA	-	-	-	-	0,2338
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	-	163	109	66,87	54	33,13	1,64	1,41	4,17	2,49	1,82	3,42	0,0000	0,7833
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	-	173	62	35,84	111	64,16	NA	18,46	NA	-	-	-	-	0,7833
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	-	32	22	68,75	10	31,25	1,45	0,72	NA	2,23	1,08	4,61	0,0267	0,7833
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	-	31	15	48,39	16	51,61	NA	1,45	NA	-	-	-	-	0,7833
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	-	18	14	77,78	4	22,22	2,32	0,69	NA	5,87	1,25	27,69	0,0129	0,2642
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	-	17	5	29,41	12	70,59	NA	10,12	NA	-	-	-	-	0,2642

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	-	61	44	72,13	17	27,87	1,41	0,76	3,02	1,90	1,17	3,08	0,0079	0,2642
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	-	64	31	48,44	33	51,56	19,91	2,14	NA	-	-	-	-	0,2642
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	-	47	27	57,45	20	42,55	4,17	1,38	NA	1,93	1,05	3,55	0,0307	0,2642
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	-	53	18	33,96	35	66,04	NA	18,46	NA	-	-	-	-	0,2642
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	-	69	46	66,67	23	33,33	2,10	1,41	6,97	3,26	1,93	5,49	0,0000	0,2642
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	-	70	23	32,86	47	67,14	NA	14,39	NA	-	-	-	-	0,2642
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	-	117	77	65,81	40	34,19	1,64	1,38	4,86	2,06	1,44	2,94	0,0001	0,1224
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	-	136	54	39,71	82	60,29	19,91	18,46	NA	-	-	-	-	0,1224
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	-	78	54	69,23	24	30,77	1,61	1,41	4,17	3,36	2,02	5,60	0,0000	0,1224
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	-	68	23	33,82	45	66,18	NA	12,91	NA	-	-	-	-	0,1224
Patients with at least one AE	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	-	34	20	58,82	14	41,18	2,83	1,41	NA	1,94	0,95	3,96	0,0629	0,5737
Patients with at least one AE	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	-	42	16	38,10	26	61,90	NA	10,12	NA	-	-	-	-	0,5737
Patients with at least one AE	Race	White	SVd Arm	Blood and lymphatic system disorders	-	161	111	68,94	50	31,06	1,64	1,18	3,78	2,43	1,77	3,35	0,0000	0,5737
Patients with at least one AE	Race	White	Vd Arm	Blood and lymphatic system disorders	-	162	61	37,65	101	62,35	20,47	18,46	NA	-	-	-	-	0,5737
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	-	6	5	83,33	1	16,67	0,82	0,03	NA	2,88	0,32	26,18	0,3270	0,8615
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	-	5	2	40,00	3	60,00	NA	1,05	NA	-	-	-	-	0,8615
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	-	171	115	67,25	56	32,75	1,64	1,41	4,17	2,36	1,75	3,19	0,0000	0,8615
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	-	185	71	38,38	114	61,62	20,47	14,39	NA	-	-	-	-	0,8615
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	-	48	34	70,83	14	29,17	2,14	1,41	4,86	3,60	1,89	6,86	0,0000	0,1566

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	-	47	13	27,66	34	72,34	NA	19,91	NA	-	-	-	-	0,1566
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	-	147	97	65,99	50	34,01	1,61	1,41	4,17	2,14	1,55	2,95	0,0000	0,1566
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	-	157	64	40,76	93	59,24	20,47	12,45	NA	-	-	-	-	0,1566
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	-	98	71	72,45	27	27,55	1,45	1,18	3,98	2,96	1,97	4,46	0,0000	0,1375
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	-	104	37	35,58	67	64,42	20,47	12,91	NA	-	-	-	-	0,1375
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	-	97	60	61,86	37	38,14	2,10	1,41	7,62	1,92	1,28	2,87	0,0012	0,1375
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	-	100	40	40,00	60	60,00	NA	14,39	NA	-	-	-	-	0,1375
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	-	98	63	64,29	35	35,71	2,14	1,41	7,43	2,54	1,68	3,84	0,0000	0,6007
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	-	111	37	33,33	74	66,67	NA	20,47	NA	-	-	-	-	0,6007
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	-	97	68	70,10	29	29,90	1,61	0,76	3,98	2,18	1,45	3,27	0,0001	0,6007
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	-	93	40	43,01	53	56,99	18,46	5,82	NA	-	-	-	-	0,6007
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	-	61	41	67,21	20	32,79	2,56	1,41	10,64	2,83	1,62	4,93	0,0001	0,4929
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	-	62	19	30,65	43	69,35	NA	19,91	NA	-	-	-	-	0,4929
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	-	134	90	67,16	44	32,84	1,45	1,38	4,14	2,25	1,60	3,16	0,0000	0,4929
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	-	142	58	40,85	84	59,15	20,47	12,45	NA	-	-	-	-	0,4929
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Blood and lymphatic system disorders	-	195	96	49,23	99	50,77	9,92	4,17	NA	2,36	1,66	3,35	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Blood and lymphatic system disorders	-	204	48	23,53	156	76,47	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Blood and lymphatic system disorders	-	80	37	46,25	43	53,75	15,44	4,17	NA	2,97	1,63	5,41	0,0002	0,5331

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Blood and lymphatic system disorders	-	91	21	23,08	70	76,92	NA	NA	NA	-	-	-	-	0,5331
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Blood and lymphatic system disorders	-	115	59	51,30	56	48,70	9,79	4,04	NA	2,34	1,47	3,71	0,0002	0,5331
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Blood and lymphatic system disorders	-	113	27	23,89	86	76,11	NA	NA	NA	-	-	-	-	0,5331
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	-	86	45	52,33	41	47,67	9,92	4,17	NA	2,58	1,48	4,50	0,0005	0,6910
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	-	75	18	24,00	57	76,00	NA	NA	NA	-	-	-	-	0,6910
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	-	109	51	46,79	58	53,21	24,48	2,99	NA	2,23	1,41	3,52	0,0004	0,6910
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	-	129	30	23,26	99	76,74	NA	NA	NA	-	-	-	-	0,6910
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	-	173	84	48,55	89	51,45	15,44	4,17	NA	2,39	1,63	3,51	0,0000	0,5795
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	-	174	39	22,41	135	77,59	NA	NA	NA	-	-	-	-	0,5795
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	-	12	7	58,33	5	41,67	3,29	1,94	NA	1,67	0,50	5,56	0,3982	0,5795
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	-	16	7	43,75	9	56,25	10,97	2,10	NA	-	-	-	-	0,5795
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	-	163	81	49,69	82	50,31	9,92	4,17	NA	2,56	1,73	3,79	0,0000	0,3300
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	-	173	37	21,39	136	78,61	NA	NA	NA	-	-	-	-	0,3300
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	-	32	15	46,88	17	53,12	4,17	2,10	NA	1,64	0,74	3,66	0,2198	0,3300
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	-	31	11	35,48	20	64,52	NA	10,97	NA	-	-	-	-	0,3300
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	-	18	9	50,00	9	50,00	9,79	2,99	NA	3,42	0,69	16,89	0,1100	0,8538

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	-	17	5	29,41	12	70,59	NA	10,12	NA	-	-	-	-	0,8538
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	-	61	36	59,02	25	40,98	3,94	1,74	NA	2,20	1,25	3,87	0,0050	0,8538
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	-	64	19	29,69	45	70,31	NA	NA	NA	-	-	-	-	0,8538
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	-	47	17	36,17	30	63,83	NA	9,92	NA	2,10	0,93	4,77	0,0690	0,8538
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	-	53	9	16,98	44	83,02	NA	NA	NA	-	-	-	-	0,8538
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	-	69	34	49,28	35	50,72	15,44	4,04	NA	2,94	1,59	5,43	0,0003	0,8538
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	-	70	15	21,43	55	78,57	NA	NA	NA	-	-	-	-	0,8538
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	-	117	54	46,15	63	53,85	15,90	4,17	NA	1,99	1,28	3,08	0,0018	0,2121
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	-	136	33	24,26	103	75,74	NA	NA	NA	-	-	-	-	0,2121
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	-	78	42	53,85	36	46,15	4,21	2,79	NA	3,18	1,76	5,77	0,0001	0,2121
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	-	68	15	22,06	53	77,94	NA	NA	NA	-	-	-	-	0,2121
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	-	34	13	38,24	21	61,76	NA	4,17	NA	1,65	0,70	3,89	0,2531	0,4147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	-	42	10	23,81	32	76,19	NA	NA	NA	-	-	-	-	0,4147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Blood and lymphatic system disorders	-	161	83	51,55	78	48,45	9,79	3,75	NA	2,44	1,65	3,60	0,0000	0,4147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Blood and lymphatic system disorders	-	162	38	23,46	124	76,54	NA	NA	NA	-	-	-	-	0,4147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	-	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	-	171	82	47,95	89	52,05	15,44	4,17	NA	2,19	1,52	3,16	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	-	185	45	24,32	140	75,68	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	-	48	23	47,92	25	52,08	4,93	3,75	NA	2,84	1,30	6,18	0,0062	0,6020
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	-	47	9	19,15	38	80,85	NA	NA	NA	-	-	-	-	0,6020
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	-	147	73	49,66	74	50,34	9,92	4,14	NA	2,25	1,52	3,32	0,0000	0,6020
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	-	157	39	24,84	118	75,16	NA	NA	NA	-	-	-	-	0,6020
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	-	98	52	53,06	46	46,94	4,93	3,25	NA	3,25	1,94	5,47	0,0000	0,0845
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	-	104	20	19,23	84	80,77	NA	NA	NA	-	-	-	-	0,0845
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	-	97	44	45,36	53	54,64	18,63	4,17	NA	1,75	1,09	2,82	0,0200	0,0845
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	-	100	28	28,00	72	72,00	NA	NA	NA	-	-	-	-	0,0845
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	-	98	41	41,84	57	58,16	44,52	4,93	NA	2,08	1,24	3,50	0,0047	0,6498
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	-	111	23	20,72	88	79,28	NA	NA	NA	-	-	-	-	0,6498
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	-	97	55	56,70	42	43,30	4,17	2,10	NA	2,45	1,51	3,98	0,0002	0,6498
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	-	93	25	26,88	68	73,12	NA	NA	NA	-	-	-	-	0,6498

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	-	61	27	44,26	34	55,74	24,48	4,17	NA	2,82	1,39	5,73	0,0028	0,6286
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	-	62	11	17,74	51	82,26	NA	NA	NA	-	-	-	-	0,6286
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	-	134	69	51,49	65	48,51	9,79	3,94	NA	2,31	1,54	3,46	0,0000	0,6286
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	-	142	37	26,06	105	73,94	NA	NA	NA	-	-	-	-	0,6286
Patients with at least one SAE	total	-	SVd Arm	Blood and lymphatic system disorders	-	195	10	5,13	185	94,87	NA	44,52	NA	1,57	0,51	4,84	0,4252	NA
Patients with at least one SAE	total	-	Vd Arm	Blood and lymphatic system disorders	-	204	5	2,45	199	97,55	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	Blood and lymphatic system disorders	-	80	2	2,50	78	97,50	NA	33,38	NA	0,36	0,04	3,45	0,3524	0,1256
Patients with at least one SAE	Gender	Female	Vd Arm	Blood and lymphatic system disorders	-	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,1256
Patients with at least one SAE	Gender	Male	SVd Arm	Blood and lymphatic system disorders	-	115	8	6,96	107	93,04	NA	44,52	NA	3,09	0,64	14,93	0,1396	0,1256
Patients with at least one SAE	Gender	Male	Vd Arm	Blood and lymphatic system disorders	-	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,1256
Patients with at least one SAE	Age Group	<65	SVd Arm	Blood and lymphatic system disorders	-	86	4	4,65	82	95,35	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Age Group	<65	Vd Arm	Blood and lymphatic system disorders	-	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Age Group	>=65	SVd Arm	Blood and lymphatic system disorders	-	109	6	5,50	103	94,50	NA	44,52	NA	1,04	0,30	3,64	0,9505	NA
Patients with at least one SAE	Age Group	>=65	Vd Arm	Blood and lymphatic system disorders	-	129	5	3,88	124	96,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	-	173	9	5,20	164	94,80	NA	44,52	NA	1,31	0,41	4,17	0,6439	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	-	174	5	2,87	169	97,13	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	-	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	-	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	Blood and lymphatic system disorders	-	163	8	4,91	155	95,09	NA	44,52	NA	1,51	0,42	5,38	0,5206	0,7548
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	Blood and lymphatic system disorders	-	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	0,7548
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	Blood and lymphatic system disorders	-	32	2	6,25	30	93,75	NA	NA	NA	2,33	0,21	25,83	0,4774	0,7548
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	Blood and lymphatic system disorders	-	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,7548

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	Blood and lymphatic system disorders	-	18	0	0,00	18	100,00	NA	NA	NA	NA	NA	NA	1,0000	0,4228
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	Blood and lymphatic system disorders	-	17	0	0,00	17	100,00	NA	NA	NA	-	-	-	-	0,4228
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	Blood and lymphatic system disorders	-	61	3	4,92	58	95,08	44,52	NA	NA	2,94	0,25	35,29	0,3760	0,4228
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	Blood and lymphatic system disorders	-	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,4228
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	Blood and lymphatic system disorders	-	47	3	6,38	44	93,62	NA	NA	NA	0,62	0,10	3,70	0,5926	0,4228
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	Blood and lymphatic system disorders	-	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,4228
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	Blood and lymphatic system disorders	-	69	4	5,80	65	94,20	NA	33,38	NA	3,38	0,35	32,49	0,2630	0,4228
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	Blood and lymphatic system disorders	-	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,4228
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Blood and lymphatic system disorders	-	117	5	4,27	112	95,73	NA	44,52	NA	0,63	0,15	2,64	0,5208	NA
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Blood and lymphatic system disorders	-	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	Blood and lymphatic system disorders	-	78	5	6,41	73	93,59	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	Blood and lymphatic system disorders	-	68	0	0,00	68	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Race	Races other than White	SVd Arm	Blood and lymphatic system disorders	-	34	2	5,88	32	94,12	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Race	Races other than White	Vd Arm	Blood and lymphatic system disorders	-	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Race	White	SVd Arm	Blood and lymphatic system disorders	-	161	8	4,97	153	95,03	NA	44,52	NA	1,13	0,34	3,76	0,8382	NA
Patients with at least one SAE	Race	White	Vd Arm	Blood and lymphatic system disorders	-	162	5	3,09	157	96,91	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Blood and lymphatic system disorders	-	171	7	4,09	164	95,91	NA	44,52	NA	1,06	0,31	3,68	0,9255	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Blood and lymphatic system disorders	-	185	5	2,70	180	97,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	Blood and lymphatic system disorders	-	48	3	6,25	45	93,75	NA	33,38	NA	1,55	0,14	17,53	0,7207	0,9895
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	Blood and lymphatic system disorders	-	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,9895
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	Blood and lymphatic system disorders	-	147	7	4,76	140	95,24	NA	44,52	NA	1,58	0,44	5,61	0,4757	0,9895
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	Blood and lymphatic system disorders	-	157	4	2,55	153	97,45	NA	NA	NA	-	-	-	-	0,9895
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	Blood and lymphatic system disorders	-	98	7	7,14	91	92,86	44,52	NA	NA	3,00	0,60	14,97	0,1610	0,2123
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	Blood and lymphatic system disorders	-	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	0,2123
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	Blood and lymphatic system disorders	-	97	3	3,09	94	96,91	NA	NA	NA	0,65	0,11	3,88	0,6310	0,2123
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	Blood and lymphatic system disorders	-	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,2123
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	Blood and lymphatic system disorders	-	98	6	6,12	92	93,88	44,52	44,52	NA	1,06	0,26	4,39	0,9330	0,3652
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	Blood and lymphatic system disorders	-	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	0,3652
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	Blood and lymphatic system disorders	-	97	4	4,12	93	95,88	NA	NA	NA	3,56	0,40	32,02	0,2271	0,3652
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	Blood and lymphatic system disorders	-	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,3652
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	Blood and lymphatic system disorders	-	61	3	4,92	58	95,08	NA	NA	NA	1,55	0,14	17,53	0,7207	0,9628
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	Blood and lymphatic system disorders	-	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,9628
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	Blood and lymphatic system disorders	-	134	7	5,22	127	94,78	NA	44,52	NA	1,66	0,46	5,91	0,4331	0,9628
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	Blood and lymphatic system disorders	-	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,9628
Patients with at least one AE	total	-	SVd Arm	Nervous system disorders	-	195	109	55,90	86	44,10	5,68	4,63	8,08	0,83	0,64	1,08	0,1590	NA
Patients with at least one AE	total	-	Vd Arm	Nervous system disorders	-	204	127	62,25	77	37,75	3,45	2,76	5,19	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Cardiac disorders	-	80	13	16,25	67	83,75	NA	NA	NA	1,92	0,73	5,03	0,1766	0,6096

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Female	Vd Arm	Cardiac disorders	-	91	8	8,79	83	91,21	NA	NA	NA	-	-	-	-	0,6096
Patients with at least one AE	Gender	Male	SVd Arm	Cardiac disorders	-	115	22	19,13	93	80,87	NA	36,60	NA	2,67	1,18	6,06	0,0145	0,6096
Patients with at least one AE	Gender	Male	Vd Arm	Cardiac disorders	-	113	8	7,08	105	92,92	NA	NA	NA	-	-	-	-	0,6096
Patients with at least one AE	Age Group	<65	SVd Arm	Cardiac disorders	-	86	16	18,60	70	81,40	NA	36,60	NA	5,92	1,33	26,26	0,0084	0,1355
Patients with at least one AE	Age Group	<65	Vd Arm	Cardiac disorders	-	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,1355
Patients with at least one AE	Age Group	>=65	SVd Arm	Cardiac disorders	-	109	19	17,43	90	82,57	NA	23,43	NA	1,69	0,83	3,41	0,1415	0,1355
Patients with at least one AE	Age Group	>=65	Vd Arm	Cardiac disorders	-	129	14	10,85	115	89,15	NA	NA	NA	-	-	-	-	0,1355
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Cardiac disorders	-	173	29	16,76	144	83,24	NA	NA	NA	1,97	1,03	3,77	0,0370	0,6681
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Cardiac disorders	-	174	14	8,05	160	91,95	NA	NA	NA	-	-	-	-	0,6681
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Cardiac disorders	-	12	5	41,67	7	58,33	14,75	4,17	NA	3,32	0,33	33,03	0,2852	0,6681
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Cardiac disorders	-	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,6681
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Cardiac disorders	-	163	26	15,95	137	84,05	NA	NA	NA	1,83	0,96	3,50	0,0617	0,1722
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Cardiac disorders	-	173	15	8,67	158	91,33	NA	NA	NA	-	-	-	-	0,1722
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Cardiac disorders	-	32	9	28,12	23	71,88	14,75	11,53	NA	8,57	1,03	71,05	0,0194	0,1722
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Cardiac disorders	-	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,1722
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Cardiac disorders	-	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,9335
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Cardiac disorders	-	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,9335
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Cardiac disorders	-	61	9	14,75	52	85,25	NA	NA	NA	1,88	0,63	5,65	0,2522	0,9335
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Cardiac disorders	-	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,9335
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Cardiac disorders	-	47	9	19,15	38	80,85	NA	NA	NA	1,98	0,60	6,55	0,2551	0,9335
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Cardiac disorders	-	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,9335
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Cardiac disorders	-	69	14	20,29	55	79,71	36,60	36,60	NA	2,44	0,92	6,46	0,0640	0,9335
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Cardiac disorders	-	70	6	8,57	64	91,43	NA	NA	NA	-	-	-	-	0,9335
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Cardiac disorders	-	117	20	17,09	97	82,91	NA	NA	NA	2,54	1,14	5,66	0,0184	0,6767
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Cardiac disorders	-	136	9	6,62	127	93,38	NA	NA	NA	-	-	-	-	0,6767
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Cardiac disorders	-	78	15	19,23	63	80,77	36,60	36,60	NA	1,96	0,77	4,95	0,1483	0,6767
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Cardiac disorders	-	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,6767
Patients with at least one AE	Race	Races other than White	SVd Arm	Cardiac disorders	-	34	8	23,53	26	76,47	NA	14,75	NA	2,07	0,58	7,33	0,2525	0,8847
Patients with at least one AE	Race	Races other than White	Vd Arm	Cardiac disorders	-	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,8847

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	SVd Arm	Cardiac disorders	-	161	27	16,77	134	83,23	NA	36,60	NA	2,30	1,13	4,69	0,0185	0,8847
Patients with at least one AE	Race	White	Vd Arm	Cardiac disorders	-	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	0,8847
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Cardiac disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Cardiac disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Cardiac disorders	-	171	31	18,13	140	81,87	NA	36,60	NA	2,26	1,21	4,22	0,0089	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Cardiac disorders	-	185	15	8,11	170	91,89	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Cardiac disorders	-	48	7	14,58	41	85,42	NA	36,60	NA	0,85	0,27	2,67	0,7834	0,0586
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Cardiac disorders	-	47	6	12,77	41	87,23	NA	NA	NA	-	-	-	-	0,0586
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Cardiac disorders	-	147	28	19,05	119	80,95	NA	NA	NA	3,15	1,52	6,52	0,0012	0,0586
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Cardiac disorders	-	157	10	6,37	147	93,63	NA	NA	NA	-	-	-	-	0,0586
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Cardiac disorders	-	98	13	13,27	85	86,73	NA	NA	NA	1,91	0,78	4,67	0,1477	0,6479
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Cardiac disorders	-	104	8	7,69	96	92,31	NA	NA	NA	-	-	-	-	0,6479
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Cardiac disorders	-	97	22	22,68	75	77,32	NA	36,60	NA	2,54	1,12	5,75	0,0208	0,6479
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Cardiac disorders	-	100	8	8,00	92	92,00	NA	NA	NA	-	-	-	-	0,6479
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Cardiac disorders	-	98	18	18,37	80	81,63	NA	36,60	NA	2,40	1,02	5,66	0,0387	0,8325
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Cardiac disorders	-	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,8325
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Cardiac disorders	-	97	17	17,53	80	82,47	NA	NA	NA	2,11	0,89	4,98	0,0817	0,8325
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Cardiac disorders	-	93	8	8,60	85	91,40	NA	NA	NA	-	-	-	-	0,8325
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Cardiac disorders	-	61	12	19,67	49	80,33	NA	36,60	NA	1,26	0,46	3,44	0,6512	0,1807

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Cardiac disorders	-	62	7	11,29	55	88,71	NA	NA	NA	-	-	-	-	0,1807
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Cardiac disorders	-	134	23	17,16	111	82,84	NA	NA	NA	3,01	1,37	6,65	0,0043	0,1807
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Cardiac disorders	-	142	9	6,34	133	93,66	NA	NA	NA	-	-	-	-	0,1807
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Cardiac disorders	-	195	13	6,67	182	93,33	NA	NA	NA	1,44	0,61	3,41	0,4089	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Cardiac disorders	-	204	9	4,41	195	95,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Cardiac disorders	-	80	7	8,75	73	91,25	NA	NA	NA	1,83	0,49	6,75	0,3614	0,8300
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Cardiac disorders	-	91	5	5,49	86	94,51	NA	NA	NA	-	-	-	-	0,8300
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Cardiac disorders	-	115	6	5,22	109	94,78	NA	NA	NA	1,49	0,42	5,32	0,5323	0,8300
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Cardiac disorders	-	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,8300
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Cardiac disorders	-	86	3	3,49	83	96,51	NA	NA	NA	2,44	0,24	24,89	0,4397	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Cardiac disorders	-	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Cardiac disorders	-	109	10	9,17	99	90,83	NA	NA	NA	1,31	0,51	3,36	0,5733	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Cardiac disorders	-	129	8	6,20	121	93,80	NA	NA	NA	-	-	-	-	0,6272
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Cardiac disorders	-	173	12	6,94	161	93,06	NA	NA	NA	1,33	0,53	3,31	0,5410	0,9835
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Cardiac disorders	-	174	8	4,60	166	95,40	NA	NA	NA	-	-	-	-	0,9835
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Cardiac disorders	-	12	1	8,33	11	91,67	NA	NA	NA	1,37	0,09	21,95	0,8236	0,9835

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Cardiac disorders	-	16	1	6,25	15	93,75	NA	NA	NA	-	-	-	-	0,9835
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Cardiac disorders	-	163	11	6,75	152	93,25	NA	NA	NA	1,29	0,51	3,28	0,5924	0,7074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Cardiac disorders	-	173	8	4,62	165	95,38	NA	NA	NA	-	-	-	-	0,7074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Cardiac disorders	-	32	2	6,25	30	93,75	NA	NA	NA	2,12	0,19	23,53	0,5327	0,7074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Cardiac disorders	-	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,7074
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Cardiac disorders	-	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,9199
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Cardiac disorders	-	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,9199
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Cardiac disorders	-	61	2	3,28	59	96,72	NA	NA	NA	1,19	0,17	8,47	0,8639	0,9199
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Cardiac disorders	-	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	0,9199
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Cardiac disorders	-	47	7	14,89	40	85,11	NA	NA	NA	1,49	0,42	5,24	0,5307	0,9199
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Cardiac disorders	-	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,9199
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Cardiac disorders	-	69	4	5,80	65	94,20	NA	NA	NA	2,02	0,36	11,23	0,4113	0,9199
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Cardiac disorders	-	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,9199
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Cardiac disorders	-	117	8	6,84	109	93,16	NA	NA	NA	1,21	0,43	3,45	0,7186	0,5804
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Cardiac disorders	-	136	7	5,15	129	94,85	NA	NA	NA	-	-	-	-	0,5804
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Cardiac disorders	-	78	5	6,41	73	93,59	NA	NA	NA	2,13	0,39	11,69	0,3731	0,5804

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Cardiac disorders	-	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,5804
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Cardiac disorders	-	34	1	2,94	33	97,06	NA	NA	NA	1,15	0,07	20,51	0,9219	0,9387
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Cardiac disorders	-	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,9387
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Cardiac disorders	-	161	12	7,45	149	92,55	NA	NA	NA	1,30	0,53	3,21	0,5691	0,9387
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Cardiac disorders	-	162	8	4,94	154	95,06	NA	NA	NA	-	-	-	-	0,9387
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Cardiac disorders	-	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Cardiac disorders	-	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Cardiac disorders	-	171	12	7,02	159	92,98	NA	NA	NA	1,39	0,58	3,35	0,4572	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Cardiac disorders	-	185	9	4,86	176	95,14	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Cardiac disorders	-	48	3	6,25	45	93,75	NA	NA	NA	0,60	0,13	2,70	0,4977	0,1669
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Cardiac disorders	-	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,1669
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Cardiac disorders	-	147	10	6,80	137	93,20	NA	NA	NA	2,22	0,75	6,62	0,1425	0,1669
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Cardiac disorders	-	157	5	3,18	152	96,82	NA	NA	NA	-	-	-	-	0,1669
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Cardiac disorders	-	98	7	7,14	91	92,86	NA	NA	NA	1,66	0,52	5,32	0,3890	0,7139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Cardiac disorders	-	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,7139

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Cardiac disorders	-	97	6	6,19	91	93,81	NA	NA	NA	1,20	0,33	4,32	0,7792	0,7139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Cardiac disorders	-	100	4	4,00	96	96,00	NA	NA	NA	-	-	-	-	0,7139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Cardiac disorders	-	98	5	5,10	93	94,90	NA	NA	NA	0,90	0,25	3,24	0,8772	0,4632
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Cardiac disorders	-	111	5	4,50	106	95,50	NA	NA	NA	-	-	-	-	0,4632
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Cardiac disorders	-	97	8	8,25	89	91,75	NA	NA	NA	1,75	0,51	5,99	0,3636	0,4632
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Cardiac disorders	-	93	4	4,30	89	95,70	NA	NA	NA	-	-	-	-	0,4632
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Cardiac disorders	-	61	7	11,48	54	88,52	NA	NA	NA	0,99	0,28	3,52	0,9881	0,4737
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Cardiac disorders	-	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,4737
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Cardiac disorders	-	134	6	4,48	128	95,52	NA	NA	NA	1,94	0,51	7,30	0,3220	0,4737
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Cardiac disorders	-	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,4737
Patients with at least one SAE	total	-	SVd Arm	Cardiac disorders	-	195	14	7,18	181	92,82	NA	NA	NA	1,35	0,59	3,08	0,4724	NA
Patients with at least one SAE	total	-	Vd Arm	Cardiac disorders	-	204	10	4,90	194	95,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	Cardiac disorders	-	80	6	7,50	74	92,50	NA	NA	NA	1,31	0,34	5,05	0,6901	0,8131
Patients with at least one SAE	Gender	Female	Vd Arm	Cardiac disorders	-	91	5	5,49	86	94,51	NA	NA	NA	-	-	-	-	0,8131
Patients with at least one SAE	Gender	Male	SVd Arm	Cardiac disorders	-	115	8	6,96	107	93,04	NA	NA	NA	1,62	0,53	5,00	0,3935	0,8131
Patients with at least one SAE	Gender	Male	Vd Arm	Cardiac disorders	-	113	5	4,42	108	95,58	NA	NA	NA	-	-	-	-	0,8131
Patients with at least one SAE	Age Group	<65	SVd Arm	Cardiac disorders	-	86	4	4,65	82	95,35	NA	NA	NA	3,23	0,35	30,12	0,2783	0,4446
Patients with at least one SAE	Age Group	<65	Vd Arm	Cardiac disorders	-	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,4446
Patients with at least one SAE	Age Group	>=65	SVd Arm	Cardiac disorders	-	109	10	9,17	99	90,83	NA	NA	NA	1,26	0,51	3,15	0,6165	0,4446
Patients with at least one SAE	Age Group	>=65	Vd Arm	Cardiac disorders	-	129	9	6,98	120	93,02	NA	NA	NA	-	-	-	-	0,4446
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	Cardiac disorders	-	173	14	8,09	159	91,91	NA	NA	NA	1,23	0,54	2,81	0,6194	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	Cardiac disorders	-	174	10	5,75	164	94,25	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	Cardiac disorders	-	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	Cardiac disorders	-	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	Cardiac disorders	-	163	13	7,98	150	92,02	NA	NA	NA	1,24	0,53	2,87	0,6207	NA
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	Cardiac disorders	-	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	Cardiac disorders	-	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	Cardiac disorders	-	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	Cardiac disorders	-	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,9691
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	Cardiac disorders	-	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,9691
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	Cardiac disorders	-	61	3	4,92	58	95,08	NA	NA	NA	1,70	0,28	10,24	0,5571	0,9691
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	Cardiac disorders	-	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	0,9691
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	Cardiac disorders	-	47	7	14,89	40	85,11	NA	NA	NA	1,49	0,42	5,24	0,5307	0,9691
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	Cardiac disorders	-	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,9691
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	Cardiac disorders	-	69	4	5,80	65	94,20	NA	NA	NA	1,27	0,28	5,80	0,7610	0,9691
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	Cardiac disorders	-	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	0,9691
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Cardiac disorders	-	117	9	7,69	108	92,31	NA	NA	NA	1,37	0,49	3,78	0,5466	0,9153
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Cardiac disorders	-	136	7	5,15	129	94,85	NA	NA	NA	-	-	-	-	0,9153
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	Cardiac disorders	-	78	5	6,41	73	93,59	NA	NA	NA	1,51	0,33	6,82	0,5913	0,9153
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	Cardiac disorders	-	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,9153
Patients with at least one SAE	Race	Races other than White	SVd Arm	Cardiac disorders	-	34	1	2,94	33	97,06	NA	NA	NA	0,58	0,05	6,75	0,6595	0,5098
Patients with at least one SAE	Race	Races other than White	Vd Arm	Cardiac disorders	-	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,5098
Patients with at least one SAE	Race	White	SVd Arm	Cardiac disorders	-	161	13	8,07	148	91,93	NA	NA	NA	1,39	0,57	3,39	0,4624	0,5098
Patients with at least one SAE	Race	White	Vd Arm	Cardiac disorders	-	162	8	4,94	154	95,06	NA	NA	NA	-	-	-	-	0,5098
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Cardiac disorders	-	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Cardiac disorders	-	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Cardiac disorders	-	171	13	7,60	158	92,40	NA	NA	NA	1,34	0,58	3,10	0,4877	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Cardiac disorders	-	185	10	5,41	175	94,59	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	Cardiac disorders	-	48	4	8,33	44	91,67	NA	NA	NA	0,66	0,17	2,47	0,5311	0,1772
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	Cardiac disorders	-	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,1772
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	Cardiac disorders	-	147	10	6,80	137	93,20	NA	NA	NA	2,14	0,72	6,39	0,1621	0,1772
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	Cardiac disorders	-	157	5	3,18	152	96,82	NA	NA	NA	-	-	-	-	0,1772
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	Cardiac disorders	-	98	6	6,12	92	93,88	NA	NA	NA	1,35	0,41	4,53	0,6209	0,9957
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	Cardiac disorders	-	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,9957
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	Cardiac disorders	-	97	8	8,25	89	91,75	NA	NA	NA	1,35	0,44	4,17	0,6021	0,9957
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	Cardiac disorders	-	100	5	5,00	95	95,00	NA	NA	NA	-	-	-	-	0,9957
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	Cardiac disorders	-	98	7	7,14	91	92,86	NA	NA	NA	1,32	0,41	4,27	0,6418	0,9872
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	Cardiac disorders	-	111	5	4,50	106	95,50	NA	NA	NA	-	-	-	-	0,9872
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	Cardiac disorders	-	97	7	7,22	90	92,78	NA	NA	NA	1,30	0,40	4,22	0,6587	0,9872
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	Cardiac disorders	-	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,9872
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	Cardiac disorders	-	61	8	13,11	53	86,89	NA	NA	NA	0,98	0,31	3,10	0,9688	0,5111
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	Cardiac disorders	-	62	6	9,68	56	90,32	NA	NA	NA	-	-	-	-	0,5111
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	Cardiac disorders	-	134	6	4,48	128	95,52	NA	NA	NA	1,76	0,47	6,67	0,3983	0,5111
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	Cardiac disorders	-	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,5111
Patients with at least one AE	total	-	SVd Arm	Psychiatric disorders	Confusional state	195	16	8,21	179	91,79	NA	NA	NA	8,43	1,94	36,72	0,0007	NA
Patients with at least one AE	total	-	Vd Arm	Psychiatric disorders	Confusional state	204	2	0,98	202	99,02	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Ear and labyrinth disorders	-	80	5	6,25	75	93,75	NA	NA	NA	1,48	0,35	6,24	0,5941	0,1883
Patients with at least one AE	Gender	Female	Vd Arm	Ear and labyrinth disorders	-	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,1883
Patients with at least one AE	Gender	Male	SVd Arm	Ear and labyrinth disorders	-	115	9	7,83	106	92,17	NA	NA	NA	8,02	1,01	63,49	0,0191	0,1883

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Male	Vd Arm	Ear and labyrinth disorders	-	113	1	0,88	112	99,12	NA	NA	NA	-	-	-	-	0,1883
Patients with at least one AE	Age Group	<65	SVd Arm	Ear and labyrinth disorders	-	86	3	3,49	83	96,51	NA	NA	NA	1,34	0,22	8,19	0,7537	0,1635
Patients with at least one AE	Age Group	<65	Vd Arm	Ear and labyrinth disorders	-	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,1635
Patients with at least one AE	Age Group	>=65	SVd Arm	Ear and labyrinth disorders	-	109	11	10,09	98	89,91	NA	NA	NA	7,16	1,58	32,48	0,0030	0,1635
Patients with at least one AE	Age Group	>=65	Vd Arm	Ear and labyrinth disorders	-	129	2	1,55	127	98,45	NA	NA	NA	-	-	-	-	0,1635
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Ear and labyrinth disorders	-	173	13	7,51	160	92,49	NA	NA	NA	3,39	1,09	10,51	0,0249	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Ear and labyrinth disorders	-	174	4	2,30	170	97,70	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Ear and labyrinth disorders	-	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Ear and labyrinth disorders	-	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Ear and labyrinth disorders	-	163	12	7,36	151	92,64	NA	NA	NA	3,38	1,08	10,55	0,0260	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Ear and labyrinth disorders	-	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Ear and labyrinth disorders	-	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Ear and labyrinth disorders	-	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Ear and labyrinth disorders	-	18	0	0,00	18	100,00	-	-	-	-	-	-	-	0,5895
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Ear and labyrinth disorders	-	17	2	11,76	15	88,24	-	-	-	-	-	-	-	0,5895
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Ear and labyrinth disorders	-	61	6	9,84	55	90,16	-	-	-	-	-	-	-	0,5895
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Ear and labyrinth disorders	-	64	0	0,00	64	100,00	-	-	-	-	-	-	-	0,5895
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Ear and labyrinth disorders	-	47	3	6,38	44	93,62	NA	NA	NA	2,30	0,24	22,21	0,4606	0,5895
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Ear and labyrinth disorders	-	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,5895
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Ear and labyrinth disorders	-	69	5	7,25	64	92,75	NA	NA	NA	5,46	0,62	48,17	0,0898	0,5895
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Ear and labyrinth disorders	-	70	1	1,43	69	98,57	NA	NA	NA	-	-	-	-	0,5895
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Ear and labyrinth disorders	-	117	7	5,98	110	94,02	NA	NA	NA	2,73	0,70	10,62	0,1309	0,4726
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Ear and labyrinth disorders	-	136	3	2,21	133	97,79	NA	NA	NA	-	-	-	-	0,4726

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Ear and labyrinth disorders	-	78	7	8,97	71	91,03	NA	NA	NA	6,86	0,83	56,98	0,0405	0,4726
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Ear and labyrinth disorders	-	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,4726
Patients with at least one AE	Race	Races other than White	SVd Arm	Ear and labyrinth disorders	-	34	4	11,76	30	88,24	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	Races other than White	Vd Arm	Ear and labyrinth disorders	-	42	0	0,00	42	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Race	White	SVd Arm	Ear and labyrinth disorders	-	161	10	6,21	151	93,79	NA	NA	NA	2,43	0,75	7,82	0,1253	NA
Patients with at least one AE	Race	White	Vd Arm	Ear and labyrinth disorders	-	162	4	2,47	158	97,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Ear and labyrinth disorders	-	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Ear and labyrinth disorders	-	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Ear and labyrinth disorders	-	171	13	7,60	158	92,40	NA	NA	NA	3,94	1,26	12,31	0,0113	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Ear and labyrinth disorders	-	185	4	2,16	181	97,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Ear and labyrinth disorders	-	48	5	10,42	43	89,58	NA	NA	NA	5,71	0,66	49,56	0,0757	0,6664
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Ear and labyrinth disorders	-	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,6664
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Ear and labyrinth disorders	-	147	9	6,12	138	93,88	NA	NA	NA	3,27	0,88	12,14	0,0605	0,6664
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Ear and labyrinth disorders	-	157	3	1,91	154	98,09	NA	NA	NA	-	-	-	-	0,6664
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Ear and labyrinth disorders	-	98	7	7,14	91	92,86	NA	NA	NA	7,70	0,94	62,93	0,0248	0,3934
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Ear and labyrinth disorders	-	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	0,3934
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Ear and labyrinth disorders	-	97	7	7,22	90	92,78	NA	NA	NA	2,59	0,66	10,10	0,1553	0,3934
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Ear and labyrinth disorders	-	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,3934
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Ear and labyrinth disorders	-	98	7	7,14	91	92,86	NA	NA	NA	4,31	0,87	21,30	0,0529	0,6987

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Ear and labyrinth disorders	-	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,6987
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Ear and labyrinth disorders	-	97	7	7,22	90	92,78	NA	NA	NA	2,76	0,57	13,41	0,1890	0,6987
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Ear and labyrinth disorders	-	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,6987
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Ear and labyrinth disorders	-	61	5	8,20	56	91,80	NA	NA	NA	2,85	0,55	14,86	0,1950	0,6192
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Ear and labyrinth disorders	-	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,6192
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Ear and labyrinth disorders	-	134	9	6,72	125	93,28	NA	NA	NA	5,05	1,08	23,61	0,0226	0,6192
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Ear and labyrinth disorders	-	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,6192
Patients with at least one AE	total	-	SVd Arm	Psychiatric disorders	Insomnia	195	31	15,90	164	84,10	NA	NA	NA	0,97	0,59	1,59	0,8984	NA
Patients with at least one AE	total	-	Vd Arm	Psychiatric disorders	Insomnia	204	32	15,69	172	84,31	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Eye disorders	-	80	33	41,25	47	58,75	11,53	8,34	NA	2,38	1,25	4,52	0,0065	0,3923
Patients with at least one AE	Gender	Female	Vd Arm	Eye disorders	-	91	17	18,68	74	81,32	41,20	26,71	NA	-	-	-	-	0,3923
Patients with at least one AE	Gender	Male	SVd Arm	Eye disorders	-	115	45	39,13	70	60,87	12,52	11,17	29,50	1,67	1,01	2,76	0,0440	0,3923
Patients with at least one AE	Gender	Male	Vd Arm	Eye disorders	-	113	26	23,01	87	76,99	NA	18,53	NA	-	-	-	-	0,3923
Patients with at least one AE	Age Group	<65	SVd Arm	Eye disorders	-	86	39	45,35	47	54,65	12,52	7,66	26,91	1,34	0,77	2,33	0,3050	0,1168
Patients with at least one AE	Age Group	<65	Vd Arm	Eye disorders	-	75	22	29,33	53	70,67	23,13	19,12	NA	-	-	-	-	0,1168
Patients with at least one AE	Age Group	>=65	SVd Arm	Eye disorders	-	109	39	35,78	70	64,22	13,37	11,17	NA	2,48	1,45	4,25	0,0007	0,1168
Patients with at least one AE	Age Group	>=65	Vd Arm	Eye disorders	-	129	21	16,28	108	83,72	NA	26,71	NA	-	-	-	-	0,1168
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Eye disorders	-	173	72	41,62	101	58,38	12,62	10,55	25,82	2,10	1,39	3,17	0,0003	0,8325
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Eye disorders	-	174	36	20,69	138	79,31	41,20	23,13	NA	-	-	-	-	0,8325
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Eye disorders	-	12	3	25,00	9	75,00	8,90	8,90	NA	2,71	0,26	28,41	0,3893	0,8325
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Eye disorders	-	16	3	18,75	13	81,25	NA	19,12	NA	-	-	-	-	0,8325
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Eye disorders	-	163	69	42,33	94	57,67	11,96	10,51	16,99	2,07	1,38	3,10	0,0003	0,9281
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Eye disorders	-	173	38	21,97	135	78,03	41,20	23,13	NA	-	-	-	-	0,9281
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Eye disorders	-	32	9	28,12	23	71,88	26,91	8,90	NA	1,95	0,55	6,94	0,2977	0,9281
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Eye disorders	-	31	5	16,13	26	83,87	NA	19,12	NA	-	-	-	-	0,9281
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Eye disorders	-	18	8	44,44	10	55,56	12,78	2,60	NA	0,73	0,22	2,43	0,6084	0,1080

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Eye disorders	-	17	8	47,06	9	52,94	5,62	2,50	NA	-	-	-	-	0,1080
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Eye disorders	-	61	26	42,62	35	57,38	9,49	5,13	NA	1,74	0,94	3,23	0,0763	0,1080
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Eye disorders	-	64	17	26,56	47	73,44	NA	16,00	NA	-	-	-	-	0,1080
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Eye disorders	-	47	17	36,17	30	63,83	13,37	11,17	NA	7,90	1,81	34,45	0,0012	0,1080
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Eye disorders	-	53	2	3,77	51	96,23	NA	NA	NA	-	-	-	-	0,1080
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Eye disorders	-	69	27	39,13	42	60,87	16,59	11,24	NA	1,92	1,00	3,67	0,0455	0,1080
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Eye disorders	-	70	16	22,86	54	77,14	26,71	19,12	NA	-	-	-	-	0,1080
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Eye disorders	-	117	43	36,75	74	63,25	12,78	11,17	NA	1,98	1,20	3,27	0,0062	0,9174
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Eye disorders	-	136	25	18,38	111	81,62	NA	NA	NA	-	-	-	-	0,9174
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Eye disorders	-	78	35	44,87	43	55,13	12,52	8,90	25,82	2,07	1,14	3,75	0,0145	0,9174
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Eye disorders	-	68	18	26,47	50	73,53	26,71	19,12	NA	-	-	-	-	0,9174
Patients with at least one AE	Race	Races other than White	SVd Arm	Eye disorders	-	34	15	44,12	19	55,88	7,29	5,32	NA	1,76	0,81	3,82	0,1496	0,5457
Patients with at least one AE	Race	Races other than White	Vd Arm	Eye disorders	-	42	16	38,10	26	61,90	16,36	6,24	NA	-	-	-	-	0,5457
Patients with at least one AE	Race	White	SVd Arm	Eye disorders	-	161	63	39,13	98	60,87	12,78	11,53	26,91	2,32	1,46	3,69	0,0002	0,5457
Patients with at least one AE	Race	White	Vd Arm	Eye disorders	-	162	27	16,67	135	83,33	41,20	41,20	NA	-	-	-	-	0,5457
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Eye disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Eye disorders	-	5	2	40,00	3	60,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Eye disorders	-	171	69	40,35	102	59,65	11,96	10,55	25,82	2,19	1,45	3,30	0,0001	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Eye disorders	-	185	37	20,00	148	80,00	41,20	26,71	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Eye disorders	-	48	20	41,67	28	58,33	13,37	8,34	NA	1,63	0,76	3,47	0,2024	0,5187
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Eye disorders	-	47	11	23,40	36	76,60	26,71	26,71	NA	-	-	-	-	0,5187
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Eye disorders	-	147	58	39,46	89	60,54	11,96	10,51	25,82	2,17	1,40	3,37	0,0004	0,5187
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Eye disorders	-	157	32	20,38	125	79,62	41,20	23,13	NA	-	-	-	-	0,5187

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Eye disorders	-	98	40	40,82	58	59,18	11,96	8,90	25,82	1,81	1,08	3,02	0,0225	0,5325
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Eye disorders	-	104	25	24,04	79	75,96	26,71	23,13	NA	-	-	-	-	0,5325
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Eye disorders	-	97	38	39,18	59	60,82	16,99	10,51	NA	2,31	1,31	4,06	0,0030	0,5325
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Eye disorders	-	100	18	18,00	82	82,00	NA	NA	NA	-	-	-	-	0,5325
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Eye disorders	-	98	40	40,82	58	59,18	11,96	8,90	30,03	1,70	1,03	2,80	0,0356	0,3925
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Eye disorders	-	111	28	25,23	83	74,77	23,13	18,53	NA	-	-	-	-	0,3925
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Eye disorders	-	97	38	39,18	59	60,82	12,78	11,17	NA	2,39	1,31	4,38	0,0036	0,3925
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Eye disorders	-	93	15	16,13	78	83,87	NA	26,71	NA	-	-	-	-	0,3925
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Eye disorders	-	61	25	40,98	36	59,02	12,62	8,31	NA	1,63	0,83	3,21	0,1561	0,5015
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Eye disorders	-	62	14	22,58	48	77,42	NA	26,71	NA	-	-	-	-	0,5015
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Eye disorders	-	134	53	39,55	81	60,45	12,52	11,17	29,50	2,16	1,36	3,43	0,0009	0,5015
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Eye disorders	-	142	29	20,42	113	79,58	41,20	23,13	NA	-	-	-	-	0,5015
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Eye disorders	-	195	24	12,31	171	87,69	NA	30,95	NA	6,68	2,26	19,77	0,0001	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Eye disorders	-	204	4	1,96	200	98,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Eye disorders	-	80	8	10,00	72	90,00	NA	NA	NA	7,82	0,92	66,31	0,0293	0,7006
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Eye disorders	-	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,7006
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Eye disorders	-	115	16	13,91	99	86,09	36,53	26,91	NA	4,80	1,35	17,04	0,0079	0,7006

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Eye disorders	-	113	3	2,65	110	97,35	NA	NA	NA	-	-	-	-	0,7006
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Eye disorders	-	86	15	17,44	71	82,56	30,95	20,30	NA	3,41	0,94	12,47	0,0492	0,2898
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Eye disorders	-	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,2898
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Eye disorders	-	109	9	8,26	100	91,74	NA	NA	NA	12,84	1,60	103,09	0,0023	0,2898
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Eye disorders	-	129	1	0,78	128	99,22	NA	NA	NA	-	-	-	-	0,2898
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Eye disorders	-	173	23	13,29	150	86,71	NA	26,91	NA	5,80	1,95	17,25	0,0004	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Eye disorders	-	174	4	2,30	170	97,70	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Eye disorders	-	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Eye disorders	-	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Eye disorders	-	163	21	12,88	142	87,12	NA	30,95	NA	5,85	1,98	17,32	0,0003	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Eye disorders	-	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Eye disorders	-	32	3	9,38	29	90,62	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Eye disorders	-	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Eye disorders	-	18	4	22,22	14	77,78	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Eye disorders	-	17	1	5,88	16	94,12	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Eye disorders	-	61	8	13,11	53	86,89	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Eye disorders	-	64	0	0,00	64	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Eye disorders	-	47	2	4,26	45	95,74	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Eye disorders	-	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Eye disorders	-	69	10	14,49	59	85,51	36,53	25,82	NA	3,30	0,84	12,91	0,0718	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Eye disorders	-	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Eye disorders	-	117	10	8,55	107	91,45	NA	NA	NA	10,81	1,37	85,29	0,0050	0,5413
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Eye disorders	-	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,5413
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Eye disorders	-	78	14	17,95	64	82,05	36,53	20,27	NA	5,06	1,39	18,43	0,0070	0,5413
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Eye disorders	-	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,5413
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Eye disorders	-	34	4	11,76	30	88,24	NA	NA	NA	2,55	0,25	26,53	0,4188	0,4068
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Eye disorders	-	42	2	4,76	40	95,24	NA	NA	NA	-	-	-	-	0,4068
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Eye disorders	-	161	20	12,42	141	87,58	NA	30,95	NA	8,23	1,89	35,88	0,0009	0,4068
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Eye disorders	-	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	0,4068
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Eye disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Eye disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Eye disorders	-	171	20	11,70	151	88,30	NA	30,95	NA	5,75	1,90	17,39	0,0005	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Eye disorders	-	185	4	2,16	181	97,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Eye disorders	-	48	8	16,67	40	83,33	NA	36,53	NA	2,65	0,51	13,71	0,2279	0,2082
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Eye disorders	-	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,2082
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Eye disorders	-	147	16	10,88	131	89,12	NA	25,82	NA	11,02	2,48	49,02	0,0001	0,2082
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Eye disorders	-	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,2082
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Eye disorders	-	98	14	14,29	84	85,71	NA	25,82	NA	6,00	1,67	21,59	0,0020	0,7758
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Eye disorders	-	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,7758
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Eye disorders	-	97	10	10,31	87	89,69	NA	36,53	NA	8,57	1,06	69,04	0,0163	0,7758
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Eye disorders	-	100	1	1,00	99	99,00	NA	NA	NA	-	-	-	-	0,7758
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Eye disorders	-	98	13	13,27	85	86,73	36,53	30,95	NA	6,72	1,43	31,45	0,0060	0,7458
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Eye disorders	-	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,7458
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Eye disorders	-	97	11	11,34	86	88,66	NA	25,82	NA	4,69	1,02	21,51	0,0295	0,7458
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Eye disorders	-	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,7458
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Eye disorders	-	61	12	19,67	49	80,33	36,53	26,91	NA	3,16	0,64	15,71	0,1390	0,3854
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Eye disorders	-	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,3854
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Eye disorders	-	134	12	8,96	122	91,04	NA	25,82	NA	8,43	1,83	38,84	0,0013	0,3854

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Eye disorders	-	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,3854
Patients with at least one AE	total	-	SVd Arm	Psychiatric disorders	-	195	56	28,72	139	71,28	NA	NA	NA	1,30	0,87	1,94	0,1990	NA
Patients with at least one AE	total	-	Vd Arm	Psychiatric disorders	-	204	43	21,08	161	78,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Gastrointestinal disorders	-	80	61	76,25	19	23,75	0,26	0,10	1,61	2,75	1,80	4,19	0,0000	0,1626
Patients with at least one AE	Gender	Female	Vd Arm	Gastrointestinal disorders	-	91	41	45,05	50	54,95	14,62	4,07	NA	-	-	-	-	0,1626
Patients with at least one AE	Gender	Male	SVd Arm	Gastrointestinal disorders	-	115	76	66,09	39	33,91	0,99	0,33	3,98	1,85	1,29	2,65	0,0007	0,1626
Patients with at least one AE	Gender	Male	Vd Arm	Gastrointestinal disorders	-	113	52	46,02	61	53,98	8,90	3,81	NA	-	-	-	-	0,1626
Patients with at least one AE	Age Group	<65	SVd Arm	Gastrointestinal disorders	-	86	61	70,93	25	29,07	1,02	0,30	2,56	2,10	1,35	3,28	0,0008	0,8174
Patients with at least one AE	Age Group	<65	Vd Arm	Gastrointestinal disorders	-	75	33	44,00	42	56,00	35,75	3,91	NA	-	-	-	-	0,8174
Patients with at least one AE	Age Group	>=65	SVd Arm	Gastrointestinal disorders	-	109	76	69,72	33	30,28	0,49	0,16	2,46	2,25	1,59	3,17	0,0000	0,8174
Patients with at least one AE	Age Group	>=65	Vd Arm	Gastrointestinal disorders	-	129	60	46,51	69	53,49	5,65	4,07	NA	-	-	-	-	0,8174
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	-	173	121	69,94	52	30,06	0,53	0,26	1,64	2,27	1,70	3,05	0,0000	0,5473
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	-	174	75	43,10	99	56,90	14,62	4,99	NA	-	-	-	-	0,5473
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	-	12	9	75,00	3	25,00	1,45	0,49	NA	1,58	0,50	4,97	0,4291	0,5473
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	-	16	7	43,75	9	56,25	NA	0,82	NA	-	-	-	-	0,5473
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	-	163	119	73,01	44	26,99	0,30	0,16	1,05	2,29	1,72	3,05	0,0000	0,4363
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	-	173	83	47,98	90	52,02	5,75	4,07	NA	-	-	-	-	0,4363
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	-	32	18	56,25	14	43,75	4,67	1,45	NA	1,62	0,70	3,71	0,2534	0,4363
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	-	31	10	32,26	21	67,74	NA	NA	NA	-	-	-	-	0,4363
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	-	18	16	88,89	2	11,11	0,07	0,07	0,43	3,41	1,34	8,66	0,0067	0,7847
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	-	17	11	64,71	6	35,29	1,58	0,82	NA	-	-	-	-	0,7847
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	-	61	51	83,61	10	16,39	0,10	0,10	0,33	2,62	1,69	4,07	0,0000	0,7847
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	-	64	37	57,81	27	42,19	3,58	1,22	NA	-	-	-	-	0,7847
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	-	47	23	48,94	24	51,06	5,78	3,98	NA	2,33	1,15	4,75	0,0161	0,7847
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	-	53	13	24,53	40	75,47	35,75	NA	NA	-	-	-	-	0,7847

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	-	69	47	68,12	22	31,88	1,41	0,59	4,47	2,08	1,31	3,31	0,0016	0,7847
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	-	70	32	45,71	38	54,29	14,62	4,21	NA	-	-	-	-	0,7847
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	-	117	80	68,38	37	31,62	0,53	0,26	3,94	2,15	1,52	3,02	0,0000	0,9827
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	-	136	59	43,38	77	56,62	35,75	4,21	NA	-	-	-	-	0,9827
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	-	78	57	73,08	21	26,92	0,69	0,20	1,64	2,16	1,39	3,35	0,0005	0,9827
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	-	68	34	50,00	34	50,00	5,75	3,15	NA	-	-	-	-	0,9827
Patients with at least one AE	Race	Races other than White	SVd Arm	Gastrointestinal disorders	-	34	30	88,24	4	11,76	0,23	0,10	0,66	2,03	1,15	3,58	0,0126	0,7703
Patients with at least one AE	Race	Races other than White	Vd Arm	Gastrointestinal disorders	-	42	28	66,67	14	33,33	2,22	0,85	8,90	-	-	-	-	0,7703
Patients with at least one AE	Race	White	SVd Arm	Gastrointestinal disorders	-	161	107	66,46	54	33,54	1,18	0,30	3,94	2,24	1,63	3,06	0,0000	0,7703
Patients with at least one AE	Race	White	Vd Arm	Gastrointestinal disorders	-	162	65	40,12	97	59,88	35,75	5,75	NA	-	-	-	-	0,7703
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	-	6	6	100,00	0	0,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	-	5	3	60,00	2	40,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	-	171	120	70,18	51	29,82	0,66	0,30	1,64	2,23	1,67	2,97	0,0000	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	-	185	82	44,32	103	55,68	14,62	4,80	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	-	48	34	70,83	14	29,17	0,53	0,26	4,04	2,44	1,38	4,33	0,0016	0,6594
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	-	47	19	40,43	28	59,57	NA	3,58	NA	-	-	-	-	0,6594
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	-	147	103	70,07	44	29,93	0,66	0,26	1,64	2,11	1,56	2,86	0,0000	0,6594
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	-	157	74	47,13	83	52,87	7,03	4,21	NA	-	-	-	-	0,6594
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	-	98	73	74,49	25	25,51	0,31	0,20	1,28	2,32	1,60	3,37	0,0000	0,6322

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	-	104	47	45,19	57	54,81	5,75	4,17	NA	-	-	-	-	0,6322
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	-	97	64	65,98	33	34,02	0,99	0,30	3,98	2,04	1,39	2,99	0,0002	0,6322
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	-	100	46	46,00	54	54,00	14,62	3,84	NA	-	-	-	-	0,6322
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	-	98	69	70,41	29	29,59	0,72	0,26	2,63	2,07	1,43	2,98	0,0001	0,7116
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	-	111	55	49,55	56	50,45	5,65	3,15	NA	-	-	-	-	0,7116
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	-	97	68	70,10	29	29,90	0,49	0,20	1,87	2,29	1,53	3,42	0,0000	0,7116
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	-	93	38	40,86	55	59,14	NA	4,99	NA	-	-	-	-	0,7116
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	-	61	43	70,49	18	29,51	0,33	0,20	3,94	2,53	1,52	4,21	0,0002	0,6499
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	-	62	28	45,16	34	54,84	NA	3,22	NA	-	-	-	-	0,6499
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	-	134	94	70,15	40	29,85	0,82	0,26	1,64	2,20	1,60	3,04	0,0000	0,6499
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	-	142	65	45,77	77	54,23	8,90	4,21	NA	-	-	-	-	0,6499
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Gastrointestinal disorders	-	195	35	17,95	160	82,05	NA	NA	NA	5,43	2,39	12,32	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Gastrointestinal disorders	-	204	7	3,43	197	96,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Gastrointestinal disorders	-	80	18	22,50	62	77,50	NA	33,77	NA	8,18	1,87	35,82	0,0009	0,4642
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Gastrointestinal disorders	-	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,4642
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Gastrointestinal disorders	-	115	17	14,78	98	85,22	NA	NA	NA	4,11	1,37	12,33	0,0064	0,4642
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Gastrointestinal disorders	-	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,4642

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Gastrointestinal disorders	-	86	13	15,12	73	84,88	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Gastrointestinal disorders	-	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Gastrointestinal disorders	-	109	22	20,18	87	79,82	NA	NA	NA	4,50	1,82	11,16	0,0004	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Gastrointestinal disorders	-	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	-	173	32	18,50	141	81,50	NA	NA	NA	10,69	3,26	35,06	0,0000	0,2738
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	-	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	0,2738
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	-	12	2	16,67	10	83,33	NA	NA	NA	2,25	0,18	28,14	0,5215	0,2738
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	-	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,2738
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	-	163	32	19,63	131	80,37	NA	NA	NA	8,45	2,98	24,01	0,0000	0,0179
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	-	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	0,0179
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	-	32	3	9,38	29	90,62	NA	NA	NA	0,76	0,14	4,16	0,7536	0,0179
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	-	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,0179
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	-	18	6	33,33	12	66,67	-	-	-	-	-	-	-	0,9147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	-	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,9147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	-	61	12	19,67	49	80,33	NA	NA	NA	4,42	1,24	15,73	0,0123	0,9147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	-	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,9147

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	-	47	4	8,51	43	91,49	NA	NA	NA	3,64	0,40	32,89	0,2189	0,9147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	-	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,9147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	-	69	13	18,84	56	81,16	NA	33,77	NA	6,12	1,37	27,38	0,0068	0,9147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	-	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,9147
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	-	117	18	15,38	99	84,62	NA	NA	NA	5,11	1,71	15,28	0,0013	0,9316
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	-	136	4	2,94	132	97,06	NA	NA	NA	-	-	-	-	0,9316
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	-	78	17	21,79	61	78,21	NA	33,77	NA	4,75	1,38	16,34	0,0064	0,9316
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	-	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,9316
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Gastrointestinal disorders	-	34	9	26,47	25	73,53	NA	NA	NA	12,58	1,56	101,30	0,0027	0,3624
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Gastrointestinal disorders	-	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,3624
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Gastrointestinal disorders	-	161	26	16,15	135	83,85	NA	NA	NA	4,37	1,77	10,79	0,0005	0,3624
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Gastrointestinal disorders	-	162	6	3,70	156	96,30	NA	NA	NA	-	-	-	-	0,3624
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	-	171	31	18,13	140	81,87	NA	NA	NA	5,69	2,35	13,76	0,0000	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	-	185	7	3,78	178	96,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	-	48	10	20,83	38	79,17	NA	33,77	NA	2,12	0,70	6,48	0,1768	0,0483
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	-	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,0483
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	-	147	25	17,01	122	82,99	NA	NA	NA	13,32	3,15	56,26	0,0000	0,0483
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	-	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,0483
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	-	98	18	18,37	80	81,63	NA	NA	NA	4,88	1,65	14,43	0,0015	0,7787
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	-	104	4	3,85	100	96,15	NA	NA	NA	-	-	-	-	0,7787
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	-	97	17	17,53	80	82,47	NA	NA	NA	6,19	1,77	21,64	0,0012	0,7787
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	-	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,7787
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	-	98	21	21,43	77	78,57	NA	NA	NA	4,07	1,63	10,17	0,0012	0,3417
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	-	111	6	5,41	105	94,59	NA	NA	NA	-	-	-	-	0,3417
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	-	97	14	14,43	83	85,57	NA	NA	NA	12,00	1,57	91,65	0,0023	0,3417
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	-	93	1	1,08	92	98,92	NA	NA	NA	-	-	-	-	0,3417
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	-	61	12	19,67	49	80,33	NA	33,77	NA	2,25	0,82	6,21	0,1068	0,0367
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	-	62	6	9,68	56	90,32	NA	NA	NA	-	-	-	-	0,0367
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	-	134	23	17,16	111	82,84	NA	NA	NA	24,66	3,33	182,78	0,0000	0,0367

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	-	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	0,0367
Patients with at least one SAE	total	-	SVd Arm	Gastrointestinal disorders	-	195	19	9,74	176	90,26	NA	NA	NA	4,83	1,64	14,22	0,0015	NA
Patients with at least one SAE	total	-	Vd Arm	Gastrointestinal disorders	-	204	4	1,96	200	98,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	Gastrointestinal disorders	-	80	9	11,25	71	88,75	NA	NA	NA	10,72	1,34	86,02	0,0060	0,3356
Patients with at least one SAE	Gender	Female	Vd Arm	Gastrointestinal disorders	-	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,3356
Patients with at least one SAE	Gender	Male	SVd Arm	Gastrointestinal disorders	-	115	10	8,70	105	91,30	NA	NA	NA	3,21	0,87	11,78	0,0639	0,3356
Patients with at least one SAE	Gender	Male	Vd Arm	Gastrointestinal disorders	-	113	3	2,65	110	97,35	NA	NA	NA	-	-	-	-	0,3356
Patients with at least one SAE	Age Group	<65	SVd Arm	Gastrointestinal disorders	-	86	7	8,14	79	91,86	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Age Group	<65	Vd Arm	Gastrointestinal disorders	-	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Age Group	>=65	SVd Arm	Gastrointestinal disorders	-	109	12	11,01	97	88,99	NA	NA	NA	3,43	1,10	10,67	0,0239	NA
Patients with at least one SAE	Age Group	>=65	Vd Arm	Gastrointestinal disorders	-	129	4	3,10	125	96,90	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	-	173	18	10,40	155	89,60	NA	NA	NA	8,41	1,95	36,35	0,0006	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	-	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	-	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	-	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	Gastrointestinal disorders	-	163	19	11,66	144	88,34	NA	NA	NA	6,53	1,93	22,09	0,0005	NA
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	Gastrointestinal disorders	-	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	Gastrointestinal disorders	-	32	0	0,00	32	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	Gastrointestinal disorders	-	31	1	3,23	30	96,77	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	Gastrointestinal disorders	-	18	2	11,11	16	88,89	-	-	-	-	-	-	-	0,3083
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	Gastrointestinal disorders	-	17	0	0,00	17	100,00	-	-	-	-	-	-	-	0,3083
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	Gastrointestinal disorders	-	61	12	19,67	49	80,33	NA	29,31	NA	6,89	1,54	30,87	0,0034	0,3083
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	Gastrointestinal disorders	-	64	2	3,12	62	96,88	NA	NA	NA	-	-	-	-	0,3083
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	Gastrointestinal disorders	-	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,3083

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	Gastrointestinal disorders	-	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,3083
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	Gastrointestinal disorders	-	69	4	5,80	65	94,20	NA	NA	NA	2,12	0,39	11,61	0,3740	0,3083
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	Gastrointestinal disorders	-	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,3083
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Gastrointestinal disorders	-	117	13	11,11	104	88,89	NA	NA	NA	13,03	1,70	100,08	0,0014	0,1168
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Gastrointestinal disorders	-	136	1	0,74	135	99,26	NA	NA	NA	-	-	-	-	0,1168
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	Gastrointestinal disorders	-	78	6	7,69	72	92,31	NA	NA	NA	1,81	0,45	7,26	0,3941	0,1168
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	Gastrointestinal disorders	-	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,1168
Patients with at least one SAE	Race	Races other than White	SVd Arm	Gastrointestinal disorders	-	34	7	20,59	27	79,41	NA	NA	NA	8,88	1,07	73,88	0,0164	0,4626
Patients with at least one SAE	Race	Races other than White	Vd Arm	Gastrointestinal disorders	-	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,4626
Patients with at least one SAE	Race	White	SVd Arm	Gastrointestinal disorders	-	161	12	7,45	149	92,55	NA	NA	NA	3,52	0,99	12,49	0,0380	0,4626
Patients with at least one SAE	Race	White	Vd Arm	Gastrointestinal disorders	-	162	3	1,85	159	98,15	NA	NA	NA	-	-	-	-	0,4626
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	-	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	-	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Gastrointestinal disorders	-	171	16	9,36	155	90,64	NA	NA	NA	4,16	1,39	12,44	0,0057	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Gastrointestinal disorders	-	185	4	2,16	181	97,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	Gastrointestinal disorders	-	48	5	10,42	43	89,58	NA	NA	NA	1,66	0,40	6,96	0,4847	0,0883
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	Gastrointestinal disorders	-	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,0883
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	Gastrointestinal disorders	-	147	14	9,52	133	90,48	NA	NA	NA	14,40	1,89	109,52	0,0007	0,0883
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	Gastrointestinal disorders	-	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,0883

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	Gastrointestinal disorders	-	98	11	11,22	87	88,78	NA	NA	NA	5,82	1,29	26,25	0,0094	0,7115
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	Gastrointestinal disorders	-	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	0,7115
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	Gastrointestinal disorders	-	97	8	8,25	89	91,75	NA	NA	NA	3,87	0,82	18,24	0,0656	0,7115
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	Gastrointestinal disorders	-	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,7115
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	Gastrointestinal disorders	-	98	11	11,22	87	88,78	NA	NA	NA	3,15	1,00	9,95	0,0388	NA
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	Gastrointestinal disorders	-	111	4	3,60	107	96,40	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	Gastrointestinal disorders	-	97	8	8,25	89	91,75	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	Gastrointestinal disorders	-	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	Gastrointestinal disorders	-	61	7	11,48	54	88,52	NA	NA	NA	1,94	0,57	6,69	0,2829	NA
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	Gastrointestinal disorders	-	62	4	6,45	58	93,55	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	Gastrointestinal disorders	-	134	12	8,96	122	91,04	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	Gastrointestinal disorders	-	142	0	0,00	142	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	total	-	SVd Arm	Renal and urinary disorders	-	195	26	13,33	169	86,67	NA	NA	NA	1,53	0,83	2,81	0,1691	NA
Patients with at least one AE	total	-	Vd Arm	Renal and urinary disorders	-	204	18	8,82	186	91,18	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	General disorders and administration site conditions	-	80	59	73,75	21	26,25	1,99	1,41	3,94	2,27	1,47	3,50	0,0002	0,2056
Patients with at least one AE	Gender	Female	Vd Arm	General disorders and administration site conditions	-	91	37	40,66	54	59,34	NA	5,49	NA	-	-	-	-	0,2056
Patients with at least one AE	Gender	Male	SVd Arm	General disorders and administration site conditions	-	115	80	69,57	35	30,43	1,68	1,15	4,86	1,59	1,14	2,23	0,0065	0,2056
Patients with at least one AE	Gender	Male	Vd Arm	General disorders and administration site conditions	-	113	64	56,64	49	43,36	5,82	3,61	8,21	-	-	-	-	0,2056

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	<65	SVd Arm	General disorders and administration site conditions	-	86	62	72,09	24	27,91	2,14	1,41	4,07	2,02	1,30	3,13	0,0015	0,6848
Patients with at least one AE	Age Group	<65	Vd Arm	General disorders and administration site conditions	-	75	34	45,33	41	54,67	8,21	5,59	NA	-	-	-	-	0,6848
Patients with at least one AE	Age Group	>=65	SVd Arm	General disorders and administration site conditions	-	109	77	70,64	32	29,36	1,54	1,18	3,94	1,80	1,28	2,52	0,0005	0,6848
Patients with at least one AE	Age Group	>=65	Vd Arm	General disorders and administration site conditions	-	129	67	51,94	62	48,06	6,01	2,92	25,46	-	-	-	-	0,6848
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	-	173	121	69,94	52	30,06	2,10	1,41	3,71	1,62	1,23	2,13	0,0006	0,0954
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	-	174	91	52,30	83	47,70	6,11	3,48	20,67	-	-	-	-	0,0954
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	-	12	10	83,33	2	16,67	0,76	0,26	NA	5,20	1,36	19,97	0,0092	0,0954
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	-	16	5	31,25	11	68,75	NA	7,26	NA	-	-	-	-	0,0954
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	-	163	115	70,55	48	29,45	2,07	1,28	3,71	1,78	1,34	2,36	0,0001	0,4742
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	-	173	88	50,87	85	49,13	6,11	3,75	NA	-	-	-	-	0,4742
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	-	32	24	75,00	8	25,00	1,54	0,82	5,59	2,38	1,13	5,05	0,0201	0,4742
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	-	31	13	41,94	18	58,06	20,67	6,67	NA	-	-	-	-	0,4742
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	General disorders and administration site conditions	-	18	16	88,89	2	11,11	0,76	0,26	3,71	3,77	1,22	11,71	0,0143	0,0585
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	General disorders and administration site conditions	-	17	8	47,06	9	52,94	6,90	0,39	NA	-	-	-	-	0,0585
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	General disorders and administration site conditions	-	61	47	77,05	14	22,95	1,18	0,49	1,64	1,17	0,77	1,77	0,4577	0,0585
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	General disorders and administration site conditions	-	64	48	75,00	16	25,00	1,41	1,02	3,48	-	-	-	-	0,0585

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	General disorders and administration site conditions	-	47	31	65,96	16	34,04	5,98	3,71	10,71	2,24	1,20	4,21	0,0098	0,0585
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	General disorders and administration site conditions	-	53	16	30,19	37	69,81	NA	8,08	NA	-	-	-	-	0,0585
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	General disorders and administration site conditions	-	69	45	65,22	24	34,78	2,00	1,18	7,33	2,37	1,45	3,86	0,0004	0,0585
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	General disorders and administration site conditions	-	70	29	41,43	41	58,57	20,67	7,26	NA	-	-	-	-	0,0585
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	General disorders and administration site conditions	-	117	83	70,94	34	29,06	2,43	1,41	4,37	1,56	1,13	2,16	0,0070	0,1107
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	General disorders and administration site conditions	-	136	69	50,74	67	49,26	5,59	2,92	NA	-	-	-	-	0,1107
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	General disorders and administration site conditions	-	78	56	71,79	22	28,21	1,43	0,72	3,09	2,47	1,56	3,92	0,0001	0,1107
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	General disorders and administration site conditions	-	68	32	47,06	36	52,94	12,91	6,01	NA	-	-	-	-	0,1107
Patients with at least one AE	Race	Races other than White	SVd Arm	General disorders and administration site conditions	-	34	27	79,41	7	20,59	1,15	0,69	3,71	1,78	1,00	3,17	0,0492	0,9171
Patients with at least one AE	Race	Races other than White	Vd Arm	General disorders and administration site conditions	-	42	27	64,29	15	35,71	3,48	2,10	NA	-	-	-	-	0,9171
Patients with at least one AE	Race	White	SVd Arm	General disorders and administration site conditions	-	161	112	69,57	49	30,43	2,14	1,41	3,98	1,84	1,36	2,48	0,0001	0,9171
Patients with at least one AE	Race	White	Vd Arm	General disorders and administration site conditions	-	162	74	45,68	88	54,32	12,91	5,59	NA	-	-	-	-	0,9171
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	-	6	6	100,00	0	0,00	0,67	0,10	NA	4,96	0,56	43,77	0,1126	0,3841
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	-	5	4	80,00	1	20,00	2,79	2,37	NA	-	-	-	-	0,3841
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	-	171	120	70,18	51	29,82	1,87	1,28	3,71	1,87	1,42	2,48	0,0000	0,3841

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	-	185	88	47,57	97	52,43	8,08	5,82	NA	-	-	-	-	0,3841
Patients with at least one AE	Prior PI therapies	N	SVd Arm	General disorders and administration site conditions	-	48	33	68,75	15	31,25	1,84	1,18	8,87	1,86	1,07	3,24	0,0263	0,9589
Patients with at least one AE	Prior PI therapies	N	Vd Arm	General disorders and administration site conditions	-	47	21	44,68	26	55,32	8,21	3,61	NA	-	-	-	-	0,9589
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	General disorders and administration site conditions	-	147	106	72,11	41	27,89	1,87	1,25	3,71	1,83	1,36	2,46	0,0000	0,9589
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	General disorders and administration site conditions	-	157	80	50,96	77	49,04	6,67	4,76	25,46	-	-	-	-	0,9589
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	General disorders and administration site conditions	-	98	67	68,37	31	31,63	1,94	1,41	5,59	1,53	1,07	2,20	0,0199	0,1683
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	General disorders and administration site conditions	-	104	55	52,88	49	47,12	6,01	2,92	NA	-	-	-	-	0,1683
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	General disorders and administration site conditions	-	97	72	74,23	25	25,77	1,64	0,72	3,71	2,22	1,52	3,23	0,0000	0,1683
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	General disorders and administration site conditions	-	100	46	46,00	54	54,00	20,57	5,36	NA	-	-	-	-	0,1683
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	General disorders and administration site conditions	-	98	67	68,37	31	31,63	1,74	1,18	5,59	1,88	1,29	2,75	0,0008	0,5808
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	General disorders and administration site conditions	-	111	53	47,75	58	52,25	12,91	4,76	NA	-	-	-	-	0,5808
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	General disorders and administration site conditions	-	97	72	74,23	25	25,77	1,87	1,15	3,71	1,62	1,12	2,35	0,0093	0,5808
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	General disorders and administration site conditions	-	93	48	51,61	45	48,39	6,01	2,86	NA	-	-	-	-	0,5808
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	General disorders and administration site conditions	-	61	44	72,13	17	27,87	1,54	1,18	5,82	1,93	1,19	3,14	0,0066	0,9242
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	General disorders and administration site conditions	-	62	29	46,77	33	53,23	8,21	2,92	NA	-	-	-	-	0,9242
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	General disorders and administration site conditions	-	134	95	70,90	39	29,10	1,87	1,25	3,71	1,88	1,37	2,58	0,0001	0,9242

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	General disorders and administration site conditions	-	142	72	50,70	70	49,30	6,90	5,36	NA	-	-	-	-	0,9242
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	General disorders and administration site conditions	-	195	50	25,64	145	74,36	NA	NA	NA	3,55	2,01	6,26	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	General disorders and administration site conditions	-	204	16	7,84	188	92,16	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	General disorders and administration site conditions	-	80	20	25,00	60	75,00	NA	NA	NA	4,18	1,56	11,21	0,0020	0,5856
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	General disorders and administration site conditions	-	91	6	6,59	85	93,41	NA	NA	NA	-	-	-	-	0,5856
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	General disorders and administration site conditions	-	115	30	26,09	85	73,91	NA	NA	NA	2,98	1,45	6,12	0,0018	0,5856
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	General disorders and administration site conditions	-	113	10	8,85	103	91,15	NA	NA	NA	-	-	-	-	0,5856
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	General disorders and administration site conditions	-	86	17	19,77	69	80,23	NA	NA	NA	5,61	1,59	19,77	0,0030	0,4692
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	General disorders and administration site conditions	-	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,4692
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	General disorders and administration site conditions	-	109	33	30,28	76	69,72	NA	NA	NA	3,32	1,74	6,35	0,0001	0,4692
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	General disorders and administration site conditions	-	129	13	10,08	116	89,92	NA	NA	NA	-	-	-	-	0,4692
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	-	173	45	26,01	128	73,99	NA	NA	NA	3,66	1,97	6,82	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	-	174	13	7,47	161	92,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	-	12	4	33,33	8	66,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	-	16	1	6,25	15	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	-	163	38	23,31	125	76,69	NA	NA	NA	3,32	1,76	6,25	0,0001	0,5070

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	-	173	13	7,51	160	92,49	NA	NA	NA	-	-	-	-	0,5070
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	-	32	12	37,50	20	62,50	NA	3,75	NA	5,78	1,27	26,28	0,0109	0,5070
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	-	31	3	9,68	28	90,32	NA	NA	NA	-	-	-	-	0,5070
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	General disorders and administration site conditions	-	18	4	22,22	14	77,78	-	-	-	-	-	-	-	0,2215
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	General disorders and administration site conditions	-	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,2215
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	General disorders and administration site conditions	-	61	14	22,95	47	77,05	NA	NA	NA	1,40	0,61	3,22	0,4278	0,2215
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	General disorders and administration site conditions	-	64	10	15,62	54	84,38	NA	NA	NA	-	-	-	-	0,2215
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	General disorders and administration site conditions	-	47	17	36,17	30	63,83	-	-	-	-	-	-	-	0,2215
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	General disorders and administration site conditions	-	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,2215
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	General disorders and administration site conditions	-	69	15	21,74	54	78,26	NA	NA	NA	3,19	1,15	8,88	0,0194	0,2215
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	General disorders and administration site conditions	-	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,2215
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	General disorders and administration site conditions	-	117	31	26,50	86	73,50	NA	NA	NA	4,20	1,98	8,90	0,0001	0,4464
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	General disorders and administration site conditions	-	136	9	6,62	127	93,38	NA	NA	NA	-	-	-	-	0,4464
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	General disorders and administration site conditions	-	78	19	24,36	59	75,64	NA	NA	NA	2,67	1,10	6,48	0,0240	0,4464
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	General disorders and administration site conditions	-	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,4464
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	General disorders and administration site conditions	-	34	9	26,47	25	73,53	NA	9,26	NA	1,49	0,54	4,15	0,4409	0,0477

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	General disorders and administration site conditions	-	42	8	19,05	34	80,95	NA	20,57	NA	-	-	-	-	0,0477
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	General disorders and administration site conditions	-	161	41	25,47	120	74,53	NA	NA	NA	5,42	2,52	11,64	0,0000	0,0477
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	General disorders and administration site conditions	-	162	8	4,94	154	95,06	NA	NA	NA	-	-	-	-	0,0477
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	-	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	-	171	45	26,32	126	73,68	NA	NA	NA	3,54	1,96	6,39	0,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	-	185	15	8,11	170	91,89	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	General disorders and administration site conditions	-	48	10	20,83	38	79,17	NA	NA	NA	3,95	1,05	14,78	0,0291	0,8599
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	General disorders and administration site conditions	-	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,8599
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	General disorders and administration site conditions	-	147	40	27,21	107	72,79	NA	NA	NA	3,46	1,85	6,49	0,0000	0,8599
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	General disorders and administration site conditions	-	157	13	8,28	144	91,72	NA	NA	NA	-	-	-	-	0,8599
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	General disorders and administration site conditions	-	98	23	23,47	75	76,53	NA	NA	NA	5,10	1,93	13,48	0,0003	0,3386
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	General disorders and administration site conditions	-	104	5	4,81	99	95,19	NA	NA	NA	-	-	-	-	0,3386
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	General disorders and administration site conditions	-	97	27	27,84	70	72,16	NA	NA	NA	2,83	1,40	5,75	0,0026	0,3386
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	General disorders and administration site conditions	-	100	11	11,00	89	89,00	NA	NA	NA	-	-	-	-	0,3386

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	General disorders and administration site conditions	-	98	27	27,55	71	72,45	NA	NA	NA	4,01	1,87	8,62	0,0001	0,5916
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	General disorders and administration site conditions	-	111	9	8,11	102	91,89	NA	NA	NA	-	-	-	-	0,5916
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	General disorders and administration site conditions	-	97	23	23,71	74	76,29	NA	NA	NA	2,93	1,25	6,90	0,0099	0,5916
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	General disorders and administration site conditions	-	93	7	7,53	86	92,47	NA	NA	NA	-	-	-	-	0,5916
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	General disorders and administration site conditions	-	61	15	24,59	46	75,41	NA	NA	NA	4,41	1,41	13,74	0,0057	0,7767
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	General disorders and administration site conditions	-	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,7767
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	General disorders and administration site conditions	-	134	35	26,12	99	73,88	NA	NA	NA	3,64	1,83	7,22	0,0001	0,7767
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	General disorders and administration site conditions	-	142	11	7,75	131	92,25	NA	NA	NA	-	-	-	-	0,7767
Patients with at least one SAE	total	-	SVd Arm	General disorders and administration site conditions	-	195	13	6,67	182	93,33	NA	NA	NA	4,99	1,41	17,66	0,0059	NA
Patients with at least one SAE	total	-	Vd Arm	General disorders and administration site conditions	-	204	3	1,47	201	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	General disorders and administration site conditions	-	80	3	3,75	77	96,25	NA	NA	NA	3,48	0,36	33,60	0,2518	0,8253
Patients with at least one SAE	Gender	Female	Vd Arm	General disorders and administration site conditions	-	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,8253
Patients with at least one SAE	Gender	Male	SVd Arm	General disorders and administration site conditions	-	115	10	8,70	105	91,30	NA	NA	NA	4,73	1,03	21,76	0,0283	0,8253
Patients with at least one SAE	Gender	Male	Vd Arm	General disorders and administration site conditions	-	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,8253
Patients with at least one SAE	Age Group	<65	SVd Arm	General disorders and administration site conditions	-	86	6	6,98	80	93,02	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Age Group	<65	Vd Arm	General disorders and administration site conditions	-	75	0	0,00	75	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Age Group	>=65	SVd Arm	General disorders and administration site conditions	-	109	7	6,42	102	93,58	NA	NA	NA	2,75	0,70	10,72	0,1304	NA
Patients with at least one SAE	Age Group	>=65	Vd Arm	General disorders and administration site conditions	-	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	-	173	11	6,36	162	93,64	NA	NA	NA	6,37	1,39	29,12	0,0065	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	-	174	2	1,15	172	98,85	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	-	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	-	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	General disorders and administration site conditions	-	163	10	6,13	153	93,87	NA	NA	NA	3,73	1,02	13,66	0,0329	NA
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	General disorders and administration site conditions	-	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	General disorders and administration site conditions	-	32	3	9,38	29	90,62	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	General disorders and administration site conditions	-	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	General disorders and administration site conditions	-	18	1	5,56	17	94,44	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	General disorders and administration site conditions	-	17	0	0,00	17	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	General disorders and administration site conditions	-	61	6	9,84	55	90,16	NA	NA	NA	1,89	0,44	8,20	0,3862	NA
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	General disorders and administration site conditions	-	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	General disorders and administration site conditions	-	47	2	4,26	45	95,74	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	General disorders and administration site conditions	-	53	0	0,00	53	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	General disorders and administration site conditions	-	69	4	5,80	65	94,20	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	General disorders and administration site conditions	-	70	0	0,00	70	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	General disorders and administration site conditions	-	117	8	6,84	109	93,16	NA	NA	NA	4,65	0,98	22,15	0,0342	0,9966
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	General disorders and administration site conditions	-	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	0,9966
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	General disorders and administration site conditions	-	78	5	6,41	73	93,59	NA	NA	NA	4,68	0,54	40,31	0,1223	0,9966
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	General disorders and administration site conditions	-	68	1	1,47	67	98,53	NA	NA	NA	-	-	-	-	0,9966
Patients with at least one SAE	Race	Races other than White	SVd Arm	General disorders and administration site conditions	-	34	4	11,76	30	88,24	NA	NA	NA	4,71	0,50	44,66	0,1437	0,9722
Patients with at least one SAE	Race	Races other than White	Vd Arm	General disorders and administration site conditions	-	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,9722
Patients with at least one SAE	Race	White	SVd Arm	General disorders and administration site conditions	-	161	9	5,59	152	94,41	NA	NA	NA	4,94	1,05	23,20	0,0255	0,9722
Patients with at least one SAE	Race	White	Vd Arm	General disorders and administration site conditions	-	162	2	1,23	160	98,77	NA	NA	NA	-	-	-	-	0,9722
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	General disorders and administration site conditions	-	171	12	7,02	159	92,98	NA	NA	NA	5,17	1,43	18,73	0,0058	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	General disorders and administration site conditions	-	185	3	1,62	182	98,38	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	General disorders and administration site conditions	-	48	2	4,17	46	95,83	NA	NA	NA	1,19	0,16	8,65	0,8633	0,1066

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	General disorders and administration site conditions	-	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,1066
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	General disorders and administration site conditions	-	147	11	7,48	136	92,52	NA	NA	NA	12,49	1,60	97,41	0,0021	0,1066
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	General disorders and administration site conditions	-	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,1066
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	General disorders and administration site conditions	-	98	7	7,14	91	92,86	NA	NA	NA	7,95	0,97	65,47	0,0230	0,5453
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	General disorders and administration site conditions	-	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	0,5453
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	General disorders and administration site conditions	-	97	6	6,19	91	93,81	NA	NA	NA	3,51	0,70	17,56	0,1044	0,5453
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	General disorders and administration site conditions	-	100	2	2,00	98	98,00	NA	NA	NA	-	-	-	-	0,5453
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	General disorders and administration site conditions	-	98	9	9,18	89	90,82	NA	NA	NA	4,10	1,10	15,26	0,0229	NA
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	General disorders and administration site conditions	-	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	General disorders and administration site conditions	-	97	4	4,12	93	95,88	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	General disorders and administration site conditions	-	93	0	0,00	93	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	General disorders and administration site conditions	-	61	5	8,20	56	91,80	NA	NA	NA	2,75	0,49	15,30	0,2301	0,3584
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	General disorders and administration site conditions	-	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,3584
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	General disorders and administration site conditions	-	134	8	5,97	126	94,03	NA	NA	NA	9,78	1,20	79,58	0,0096	0,3584
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	General disorders and administration site conditions	-	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	0,3584
Patients with at least one AE	total	-	SVd Arm	Respiratory, thoracic and mediastinal disorders	Cough	195	35	17,95	160	82,05	NA	NA	NA	1,35	0,82	2,23	0,2383	NA
Patients with at least one AE	total	-	Vd Arm	Respiratory, thoracic and mediastinal disorders	Cough	204	28	13,73	176	86,27	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Female	SVd Arm	Infections and infestations	-	80	64	80,00	16	20,00	2,96	1,94	4,70	1,85	1,25	2,75	0,0020	0,0166
Patients with at least one AE	Gender	Female	Vd Arm	Infections and infestations	-	91	50	54,95	41	45,05	4,17	3,06	11,66	-	-	-	-	0,0166
Patients with at least one AE	Gender	Male	SVd Arm	Infections and infestations	-	115	74	64,35	41	35,65	4,57	3,32	7,13	0,98	0,71	1,37	0,9252	0,0166
Patients with at least one AE	Gender	Male	Vd Arm	Infections and infestations	-	113	70	61,95	43	38,05	4,17	2,69	6,90	-	-	-	-	0,0166
Patients with at least one AE	Age Group	<65	SVd Arm	Infections and infestations	-	86	64	74,42	22	25,58	3,94	2,69	5,68	1,56	1,04	2,34	0,0306	0,1627
Patients with at least one AE	Age Group	<65	Vd Arm	Infections and infestations	-	75	42	56,00	33	44,00	5,09	3,12	11,66	-	-	-	-	0,1627
Patients with at least one AE	Age Group	>=65	SVd Arm	Infections and infestations	-	109	74	67,89	35	32,11	3,52	2,79	5,29	1,08	0,78	1,49	0,6559	0,1627
Patients with at least one AE	Age Group	>=65	Vd Arm	Infections and infestations	-	129	78	60,47	51	39,53	3,35	2,46	6,90	-	-	-	-	0,1627
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	-	173	121	69,94	52	30,06	4,21	3,12	5,29	1,15	0,88	1,50	0,2961	0,1319
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	-	174	105	60,34	69	39,66	4,17	2,79	5,91	-	-	-	-	0,1319
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	-	12	10	83,33	2	16,67	1,94	1,87	NA	2,95	0,89	9,75	0,0647	0,1319
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	-	16	7	43,75	9	56,25	7,36	1,74	NA	-	-	-	-	0,1319
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	-	163	114	69,94	49	30,06	3,65	2,92	4,96	1,22	0,93	1,60	0,1471	0,8576
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	-	173	103	59,54	70	40,46	4,57	3,06	6,80	-	-	-	-	0,8576
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	-	32	24	75,00	8	25,00	4,17	1,94	11,10	1,31	0,65	2,61	0,4485	0,8576
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	-	31	17	54,84	14	45,16	3,06	2,20	NA	-	-	-	-	0,8576
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	-	18	9	50,00	9	50,00	4,96	3,52	NA	0,62	0,21	1,86	0,3895	0,3942
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	-	17	11	64,71	6	35,29	4,57	1,51	NA	-	-	-	-	0,3942
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	-	61	46	75,41	15	24,59	2,69	2,07	4,21	0,97	0,63	1,51	0,9063	0,3942
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	-	64	44	68,75	20	31,25	1,97	1,71	5,36	-	-	-	-	0,3942
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	-	47	35	74,47	12	25,53	4,21	2,79	6,24	1,34	0,79	2,25	0,2764	0,3942
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	-	53	27	50,94	26	49,06	4,86	2,79	NA	-	-	-	-	0,3942
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	-	69	48	69,57	21	30,43	4,57	2,53	7,82	1,42	0,92	2,20	0,1110	0,3942
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	-	70	38	54,29	32	45,71	6,01	3,65	NA	-	-	-	-	0,3942

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	-	117	84	71,79	33	28,21	3,65	2,96	5,03	1,17	0,85	1,60	0,3337	0,6209
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	-	136	80	58,82	56	41,18	3,35	2,20	6,80	-	-	-	-	0,6209
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	-	78	54	69,23	24	30,77	3,75	2,37	7,16	1,33	0,88	2,03	0,1778	0,6209
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	-	68	40	58,82	28	41,18	5,55	3,12	12,22	-	-	-	-	0,6209
Patients with at least one AE	Race	Races other than White	SVd Arm	Infections and infestations	-	34	23	67,65	11	32,35	4,57	1,61	NA	2,06	1,08	3,93	0,0267	0,1226
Patients with at least one AE	Race	Races other than White	Vd Arm	Infections and infestations	-	42	24	57,14	18	42,86	7,36	2,60	NA	-	-	-	-	0,1226
Patients with at least one AE	Race	White	SVd Arm	Infections and infestations	-	161	115	71,43	46	28,57	3,52	2,92	4,96	1,18	0,89	1,56	0,2445	0,1226
Patients with at least one AE	Race	White	Vd Arm	Infections and infestations	-	162	96	59,26	66	40,74	3,68	2,76	5,55	-	-	-	-	0,1226
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	-	6	5	83,33	1	16,67	2,56	1,87	NA	3,35	0,34	33,36	0,2769	0,4072
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	-	5	3	60,00	2	40,00	1,91	1,51	NA	-	-	-	-	0,4072
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	-	171	120	70,18	51	29,82	3,75	2,96	5,09	1,26	0,97	1,64	0,0868	0,4072
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	-	185	109	58,92	76	41,08	4,86	3,09	6,80	-	-	-	-	0,4072
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Infections and infestations	-	48	36	75,00	12	25,00	3,75	2,56	6,90	1,27	0,77	2,09	0,3536	0,9182
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Infections and infestations	-	47	28	59,57	19	40,43	5,36	2,46	NA	-	-	-	-	0,9182
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Infections and infestations	-	147	102	69,39	45	30,61	3,65	2,92	5,09	1,23	0,92	1,64	0,1547	0,9182
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Infections and infestations	-	157	92	58,60	65	41,40	4,17	2,79	6,90	-	-	-	-	0,9182
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	-	98	73	74,49	25	25,51	3,45	2,43	5,29	1,20	0,86	1,69	0,2868	0,8114
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	-	104	64	61,54	40	38,46	3,12	2,60	5,91	-	-	-	-	0,8114
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	-	97	65	67,01	32	32,99	4,14	3,02	5,55	1,28	0,89	1,83	0,1798	0,8114

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	-	100	56	56,00	44	44,00	5,55	2,73	9,89	-	-	-	-	0,8114
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	-	98	66	67,35	32	32,65	4,80	3,12	6,70	1,21	0,85	1,71	0,2921	0,8975
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	-	111	64	57,66	47	42,34	5,09	3,06	9,00	-	-	-	-	0,8975
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	-	97	72	74,23	25	25,77	2,96	2,53	4,70	1,25	0,87	1,79	0,2275	0,8975
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	-	93	56	60,22	37	39,78	4,17	2,14	7,89	-	-	-	-	0,8975
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	-	61	42	68,85	19	31,15	3,75	2,56	6,90	1,22	0,77	1,95	0,3956	0,9323
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	-	62	34	54,84	28	45,16	6,01	3,06	NA	-	-	-	-	0,9323
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	-	134	96	71,64	38	28,36	3,55	2,79	5,03	1,20	0,89	1,61	0,2354	0,9323
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	-	142	86	60,56	56	39,44	3,65	2,73	5,91	-	-	-	-	0,9323
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Infections and infestations	-	195	65	33,33	130	66,67	30,75	17,54	NA	2,03	1,34	3,08	0,0006	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Infections and infestations	-	204	36	17,65	168	82,35	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Infections and infestations	-	80	36	45,00	44	55,00	10,91	7,79	NA	4,27	2,14	8,51	0,0000	0,0075
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Infections and infestations	-	91	14	15,38	77	84,62	NA	NA	NA	-	-	-	-	0,0075
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Infections and infestations	-	115	29	25,22	86	74,78	NA	28,09	NA	1,27	0,73	2,22	0,3959	0,0075
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Infections and infestations	-	113	22	19,47	91	80,53	NA	NA	NA	-	-	-	-	0,0075
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Infections and infestations	-	86	31	36,05	55	63,95	30,75	14,03	NA	3,71	1,61	8,58	0,0011	0,0740

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Infections and infestations	-	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,0740
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Infections and infestations	-	109	34	31,19	75	68,81	NA	14,13	NA	1,52	0,92	2,52	0,1021	0,0740
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Infections and infestations	-	129	28	21,71	101	78,29	NA	NA	NA	-	-	-	-	0,0740
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	-	173	59	34,10	114	65,90	30,75	17,54	NA	2,04	1,30	3,19	0,0014	0,3139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	-	174	30	17,24	144	82,76	NA	NA	NA	-	-	-	-	0,3139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	-	12	6	50,00	6	50,00	5,65	3,06	NA	6,34	0,73	55,06	0,0597	0,3139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	-	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,3139
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	-	163	48	29,45	115	70,55	34,50	25,23	NA	1,59	1,01	2,50	0,0423	0,0176
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	-	173	32	18,50	141	81,50	NA	NA	NA	-	-	-	-	0,0176
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	-	32	17	53,12	15	46,88	7,00	3,75	NA	10,77	2,37	48,81	0,0002	0,0176
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	-	31	4	12,90	27	87,10	20,90	20,90	NA	-	-	-	-	0,0176
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Infections and infestations	-	18	2	11,11	16	88,89	NA	NA	NA	0,36	0,03	4,04	0,3913	0,5629
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Infections and infestations	-	17	3	17,65	14	82,35	NA	10,48	NA	-	-	-	-	0,5629
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Infections and infestations	-	61	20	32,79	41	67,21	25,23	11,17	NA	1,88	0,89	3,99	0,0935	0,5629
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Infections and infestations	-	64	11	17,19	53	82,81	NA	NA	NA	-	-	-	-	0,5629
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Infections and infestations	-	47	16	34,04	31	65,96	NA	10,91	NA	1,88	0,77	4,58	0,1594	0,5629

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Infections and infestations	-	53	9	16,98	44	83,02	NA	NA	NA	-	-	-	-	0,5629
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Infections and infestations	-	69	27	39,13	42	60,87	30,75	17,54	NA	2,24	1,15	4,37	0,0149	0,5629
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Infections and infestations	-	70	13	18,57	57	81,43	NA	NA	NA	-	-	-	-	0,5629
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	-	117	34	29,06	83	70,94	34,50	14,03	NA	1,78	1,03	3,07	0,0379	0,6355
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	-	136	23	16,91	113	83,09	NA	NA	NA	-	-	-	-	0,6355
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	-	78	31	39,74	47	60,26	28,09	7,98	NA	2,18	1,13	4,20	0,0167	0,6355
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	-	68	13	19,12	55	80,88	NA	NA	NA	-	-	-	-	0,6355
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Infections and infestations	-	34	14	41,18	20	58,82	17,54	5,65	NA	4,46	1,52	13,04	0,0035	0,1032
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Infections and infestations	-	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,1032
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Infections and infestations	-	161	51	31,68	110	68,32	30,75	25,23	NA	1,69	1,06	2,67	0,0246	0,1032
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Infections and infestations	-	162	31	19,14	131	80,86	NA	NA	NA	-	-	-	-	0,1032
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	-	6	4	66,67	2	33,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	-	171	55	32,16	116	67,84	30,75	25,23	NA	1,82	1,18	2,81	0,0063	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	-	185	34	18,38	151	81,62	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Infections and infestations	-	48	18	37,50	30	62,50	28,09	14,13	NA	2,06	0,90	4,69	0,0808	0,9751
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Infections and infestations	-	47	9	19,15	38	80,85	NA	NA	NA	-	-	-	-	0,9751
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Infections and infestations	-	147	47	31,97	100	68,03	34,50	12,55	NA	2,03	1,25	3,27	0,0033	0,9751
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Infections and infestations	-	157	27	17,20	130	82,80	NA	NA	NA	-	-	-	-	0,9751
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	-	98	39	39,80	59	60,20	25,23	10,05	NA	2,51	1,43	4,43	0,0010	0,2612
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	-	104	18	17,31	86	82,69	NA	NA	NA	-	-	-	-	0,2612
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	-	97	26	26,80	71	73,20	NA	30,75	NA	1,56	0,84	2,88	0,1550	0,2612
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	-	100	18	18,00	82	82,00	NA	NA	NA	-	-	-	-	0,2612
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	-	98	36	36,73	62	63,27	28,09	14,13	NA	2,79	1,53	5,09	0,0005	0,1319
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	-	111	16	14,41	95	85,59	NA	NA	NA	-	-	-	-	0,1319
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	-	97	29	29,90	68	70,10	NA	14,03	NA	1,45	0,79	2,65	0,2274	0,1319
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	-	93	20	21,51	73	78,49	NA	NA	NA	-	-	-	-	0,1319
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	-	61	21	34,43	40	65,57	30,75	14,13	NA	2,09	0,94	4,62	0,0638	0,8873
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	-	62	10	16,13	52	83,87	NA	NA	NA	-	-	-	-	0,8873
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	-	134	44	32,84	90	67,16	NA	12,55	NA	1,95	1,20	3,19	0,0066	0,8873
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	-	142	26	18,31	116	81,69	NA	NA	NA	-	-	-	-	0,8873

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	total	-	SVd Arm	Infections and infestations	-	195	56	28,72	139	71,28	34,50	25,23	NA	1,46	0,97	2,21	0,0715	NA
Patients with at least one SAE	total	-	Vd Arm	Infections and infestations	-	204	40	19,61	164	80,39	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	Infections and infestations	-	80	30	37,50	50	62,50	30,75	10,05	NA	2,42	1,28	4,59	0,0054	0,0676
Patients with at least one SAE	Gender	Female	Vd Arm	Infections and infestations	-	91	18	19,78	73	80,22	NA	NA	NA	-	-	-	-	0,0676
Patients with at least one SAE	Gender	Male	SVd Arm	Infections and infestations	-	115	26	22,61	89	77,39	NA	28,09	NA	1,08	0,61	1,93	0,7832	0,0676
Patients with at least one SAE	Gender	Male	Vd Arm	Infections and infestations	-	113	22	19,47	91	80,53	NA	NA	NA	-	-	-	-	0,0676
Patients with at least one SAE	Age Group	<65	SVd Arm	Infections and infestations	-	86	27	31,40	59	68,60	34,50	17,54	NA	2,03	0,98	4,20	0,0512	0,2351
Patients with at least one SAE	Age Group	<65	Vd Arm	Infections and infestations	-	75	11	14,67	64	85,33	NA	NA	NA	-	-	-	-	0,2351
Patients with at least one SAE	Age Group	>=65	SVd Arm	Infections and infestations	-	109	29	26,61	80	73,39	NA	24,94	NA	1,18	0,70	2,00	0,5333	0,2351
Patients with at least one SAE	Age Group	>=65	Vd Arm	Infections and infestations	-	129	29	22,48	100	77,52	NA	NA	NA	-	-	-	-	0,2351
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	Infections and infestations	-	173	53	30,64	120	69,36	30,75	25,23	NA	1,60	1,02	2,49	0,0370	0,6233
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	Infections and infestations	-	174	33	18,97	141	81,03	NA	NA	NA	-	-	-	-	0,6233
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	Infections and infestations	-	12	3	25,00	9	75,00	NA	5,65	NA	1,03	0,19	5,57	0,9712	0,6233
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	Infections and infestations	-	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,6233
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	Infections and infestations	-	163	42	25,77	121	74,23	NA	25,23	NA	1,24	0,78	1,96	0,3601	0,2369
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	Infections and infestations	-	173	34	19,65	139	80,35	NA	NA	NA	-	-	-	-	0,2369
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	Infections and infestations	-	32	14	43,75	18	56,25	12,55	6,80	NA	2,41	0,89	6,55	0,0768	0,2369
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	Infections and infestations	-	31	6	19,35	25	80,65	20,90	20,90	NA	-	-	-	-	0,2369
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	Infections and infestations	-	18	1	5,56	17	94,44	-	-	-	-	-	-	-	0,9296
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	Infections and infestations	-	17	3	17,65	14	82,35	-	-	-	-	-	-	-	0,9296
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	Infections and infestations	-	61	19	31,15	42	68,85	25,23	11,17	NA	1,66	0,79	3,49	0,1757	0,9296
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	Infections and infestations	-	64	12	18,75	52	81,25	NA	NA	NA	-	-	-	-	0,9296
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	Infections and infestations	-	47	13	27,66	34	72,34	NA	14,03	NA	1,33	0,55	3,20	0,5222	0,9296
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	Infections and infestations	-	53	10	18,87	43	81,13	NA	NA	NA	-	-	-	-	0,9296

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	Infections and infestations	-	69	23	33,33	46	66,67	30,75	24,94	NA	1,48	0,77	2,87	0,2399	0,9296
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	Infections and infestations	-	70	15	21,43	55	78,57	NA	NA	NA	-	-	-	-	0,9296
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Infections and infestations	-	117	29	24,79	88	75,21	NA	25,23	NA	1,34	0,77	2,32	0,2960	0,7766
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Infections and infestations	-	136	25	18,38	111	81,62	NA	NA	NA	-	-	-	-	0,7766
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	Infections and infestations	-	78	27	34,62	51	65,38	30,75	24,94	NA	1,51	0,80	2,88	0,2019	0,7766
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	Infections and infestations	-	68	15	22,06	53	77,94	NA	NA	NA	-	-	-	-	0,7766
Patients with at least one SAE	Race	Races other than White	SVd Arm	Infections and infestations	-	34	15	44,12	19	55,88	17,54	5,65	NA	4,99	1,71	14,53	0,0015	0,0127
Patients with at least one SAE	Race	Races other than White	Vd Arm	Infections and infestations	-	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,0127
Patients with at least one SAE	Race	White	SVd Arm	Infections and infestations	-	161	41	25,47	120	74,53	34,50	28,09	NA	1,13	0,71	1,80	0,6001	0,0127
Patients with at least one SAE	Race	White	Vd Arm	Infections and infestations	-	162	35	21,60	127	78,40	NA	NA	NA	-	-	-	-	0,0127
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Infections and infestations	-	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Infections and infestations	-	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Infections and infestations	-	171	48	28,07	123	71,93	34,50	28,09	NA	1,37	0,89	2,13	0,1544	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Infections and infestations	-	185	37	20,00	148	80,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	Infections and infestations	-	48	16	33,33	32	66,67	30,75	17,54	NA	1,48	0,66	3,30	0,3389	0,9733
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	Infections and infestations	-	47	10	21,28	37	78,72	NA	NA	NA	-	-	-	-	0,9733
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	Infections and infestations	-	147	40	27,21	107	72,79	34,50	24,94	NA	1,45	0,90	2,35	0,1265	0,9733
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	Infections and infestations	-	157	30	19,11	127	80,89	NA	NA	NA	-	-	-	-	0,9733
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	Infections and infestations	-	98	36	36,73	62	63,27	24,94	12,55	NA	1,95	1,12	3,41	0,0164	0,1113

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	Infections and infestations	-	104	20	19,23	84	80,77	NA	NA	NA	-	-	-	-	0,1113
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	Infections and infestations	-	97	20	20,62	77	79,38	NA	NA	NA	0,99	0,53	1,85	0,9669	0,1113
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	Infections and infestations	-	100	20	20,00	80	80,00	NA	NA	NA	-	-	-	-	0,1113
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	Infections and infestations	-	98	32	32,65	66	67,35	30,75	24,94	NA	1,81	1,02	3,21	0,0400	0,3351
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	Infections and infestations	-	111	20	18,02	91	81,98	NA	NA	NA	-	-	-	-	0,3351
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	Infections and infestations	-	97	24	24,74	73	75,26	NA	NA	NA	1,19	0,64	2,23	0,5851	0,3351
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	Infections and infestations	-	93	20	21,51	73	78,49	NA	NA	NA	-	-	-	-	0,3351
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	Infections and infestations	-	61	19	31,15	42	68,85	30,75	28,09	NA	1,54	0,71	3,34	0,2764	0,8279
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	Infections and infestations	-	62	11	17,74	51	82,26	NA	NA	NA	-	-	-	-	0,8279
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	Infections and infestations	-	134	37	27,61	97	72,39	NA	24,94	NA	1,39	0,84	2,27	0,1943	0,8279
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	Infections and infestations	-	142	29	20,42	113	79,58	NA	NA	NA	-	-	-	-	0,8279
Patients with at least one AE	total	-	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	195	10	5,13	185	94,87	NA	NA	NA	1,26	0,51	3,12	0,6217	NA
Patients with at least one AE	total	-	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	204	9	4,41	195	95,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Injury, poisoning and procedural complications	-	80	14	17,50	66	82,50	NA	NA	NA	1,55	0,68	3,51	0,2922	0,5513
Patients with at least one AE	Gender	Female	Vd Arm	Injury, poisoning and procedural complications	-	91	11	12,09	80	87,91	NA	NA	NA	-	-	-	-	0,5513
Patients with at least one AE	Gender	Male	SVd Arm	Injury, poisoning and procedural complications	-	115	27	23,48	88	76,52	NA	16,76	NA	2,14	1,09	4,17	0,0232	0,5513
Patients with at least one AE	Gender	Male	Vd Arm	Injury, poisoning and procedural complications	-	113	13	11,50	100	88,50	NA	NA	NA	-	-	-	-	0,5513
Patients with at least one AE	Age Group	<65	SVd Arm	Injury, poisoning and procedural complications	-	86	15	17,44	71	82,56	NA	NA	NA	1,63	0,68	3,90	0,2668	0,6648

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	<65	Vd Arm	Injury, poisoning and procedural complications	-	75	8	10,67	67	89,33	NA	NA	NA	-	-	-	-	0,6648
Patients with at least one AE	Age Group	>=65	SVd Arm	Injury, poisoning and procedural complications	-	109	26	23,85	83	76,15	NA	NA	NA	2,07	1,10	3,87	0,0205	0,6648
Patients with at least one AE	Age Group	>=65	Vd Arm	Injury, poisoning and procedural complications	-	129	16	12,40	113	87,60	NA	NA	NA	-	-	-	-	0,6648
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	-	173	37	21,39	136	78,61	NA	NA	NA	1,65	0,97	2,78	0,0601	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	-	174	23	13,22	151	86,78	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	-	12	3	25,00	9	75,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	-	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	-	163	35	21,47	128	78,53	NA	NA	NA	1,68	0,99	2,88	0,0537	0,4024
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	-	173	22	12,72	151	87,28	NA	NA	NA	-	-	-	-	0,4024
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	-	32	6	18,75	26	81,25	NA	NA	NA	3,49	0,69	17,69	0,1088	0,4024
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	-	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,4024
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Injury, poisoning and procedural complications	-	18	7	38,89	11	61,11	14,78	12,85	NA	0,81	0,19	3,39	0,7743	0,6409
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Injury, poisoning and procedural complications	-	17	4	23,53	13	76,47	NA	11,14	NA	-	-	-	-	0,6409
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Injury, poisoning and procedural complications	-	61	21	34,43	40	65,57	21,26	7,00	NA	2,25	1,06	4,80	0,0306	0,6409
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Injury, poisoning and procedural complications	-	64	10	15,62	54	84,38	NA	NA	NA	-	-	-	-	0,6409
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Injury, poisoning and procedural complications	-	47	5	10,64	42	89,36	NA	NA	NA	1,41	0,37	5,31	0,6123	0,6409

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Injury, poisoning and procedural complications	-	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,6409
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Injury, poisoning and procedural complications	-	69	8	11,59	61	88,41	NA	NA	NA	1,50	0,52	4,36	0,4534	0,6409
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Injury, poisoning and procedural complications	-	70	6	8,57	64	91,43	NA	NA	NA	-	-	-	-	0,6409
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Injury, poisoning and procedural complications	-	117	27	23,08	90	76,92	NA	21,26	NA	1,62	0,89	2,96	0,1112	0,6239
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Injury, poisoning and procedural complications	-	136	18	13,24	118	86,76	NA	NA	NA	-	-	-	-	0,6239
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Injury, poisoning and procedural complications	-	78	14	17,95	64	82,05	NA	NA	NA	2,16	0,82	5,65	0,1091	0,6239
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Injury, poisoning and procedural complications	-	68	6	8,82	62	91,18	NA	NA	NA	-	-	-	-	0,6239
Patients with at least one AE	Race	Races other than White	SVd Arm	Injury, poisoning and procedural complications	-	34	7	20,59	27	79,41	NA	NA	NA	3,84	0,96	15,38	0,0435	0,3809
Patients with at least one AE	Race	Races other than White	Vd Arm	Injury, poisoning and procedural complications	-	42	6	14,29	36	85,71	NA	19,98	NA	-	-	-	-	0,3809
Patients with at least one AE	Race	White	SVd Arm	Injury, poisoning and procedural complications	-	161	34	21,12	127	78,88	NA	NA	NA	1,96	1,10	3,49	0,0205	0,3809
Patients with at least one AE	Race	White	Vd Arm	Injury, poisoning and procedural complications	-	162	18	11,11	144	88,89	NA	NA	NA	-	-	-	-	0,3809
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	-	6	1	16,67	5	83,33	NA	NA	NA	0,47	0,03	7,86	0,5924	0,3373
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	-	5	1	20,00	4	80,00	NA	NA	NA	-	-	-	-	0,3373
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	-	171	36	21,05	135	78,95	NA	NA	NA	1,92	1,12	3,28	0,0158	0,3373
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	-	185	22	11,89	163	88,11	NA	NA	NA	-	-	-	-	0,3373

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Injury, poisoning and procedural complications	-	48	9	18,75	39	81,25	NA	NA	NA	1,93	0,64	5,80	0,2328	0,9428
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Injury, poisoning and procedural complications	-	47	5	10,64	42	89,36	NA	NA	NA	-	-	-	-	0,9428
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Injury, poisoning and procedural complications	-	147	32	21,77	115	78,23	NA	16,76	NA	1,85	1,04	3,27	0,0327	0,9428
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Injury, poisoning and procedural complications	-	157	19	12,10	138	87,90	NA	NA	NA	-	-	-	-	0,9428
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Injury, poisoning and procedural complications	-	98	21	21,43	77	78,57	NA	21,26	NA	1,72	0,86	3,44	0,1236	0,7354
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Injury, poisoning and procedural complications	-	104	13	12,50	91	87,50	NA	NA	NA	-	-	-	-	0,7354
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Injury, poisoning and procedural complications	-	97	20	20,62	77	79,38	NA	NA	NA	2,04	0,97	4,29	0,0537	0,7354
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Injury, poisoning and procedural complications	-	100	11	11,00	89	89,00	NA	NA	NA	-	-	-	-	0,7354
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Injury, poisoning and procedural complications	-	98	22	22,45	76	77,55	NA	NA	NA	2,39	1,18	4,85	0,0131	0,2707
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Injury, poisoning and procedural complications	-	111	12	10,81	99	89,19	NA	NA	NA	-	-	-	-	0,2707
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Injury, poisoning and procedural complications	-	97	19	19,59	78	80,41	NA	NA	NA	1,35	0,65	2,79	0,4166	0,2707
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Injury, poisoning and procedural complications	-	93	12	12,90	81	87,10	NA	NA	NA	-	-	-	-	0,2707
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Injury, poisoning and procedural complications	-	61	11	18,03	50	81,97	NA	NA	NA	1,86	0,67	5,15	0,2264	0,9891
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Injury, poisoning and procedural complications	-	62	6	9,68	56	90,32	NA	NA	NA	-	-	-	-	0,9891
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Injury, poisoning and procedural complications	-	134	30	22,39	104	77,61	NA	16,76	NA	1,84	1,02	3,32	0,0391	0,9891
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Injury, poisoning and procedural complications	-	142	18	12,68	124	87,32	NA	NA	NA	-	-	-	-	0,9891

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Injury, poisoning and procedural complications	-	195	11	5,64	184	94,36	NA	NA	NA	2,22	0,77	6,41	0,1298	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Injury, poisoning and procedural complications	-	204	5	2,45	199	97,55	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Injury, poisoning and procedural complications	-	80	2	2,50	78	97,50	NA	NA	NA	0,56	0,09	3,54	0,5355	0,0899
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Injury, poisoning and procedural complications	-	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,0899
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Injury, poisoning and procedural complications	-	115	9	7,83	106	92,17	NA	NA	NA	4,48	0,96	20,80	0,0364	0,0899
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Injury, poisoning and procedural complications	-	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,0899
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Injury, poisoning and procedural complications	-	86	2	2,33	84	97,67	NA	NA	NA	0,96	0,13	6,92	0,9649	0,2364
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Injury, poisoning and procedural complications	-	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,2364
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Injury, poisoning and procedural complications	-	109	9	8,26	100	91,74	NA	NA	NA	4,02	1,08	14,99	0,0255	0,2364
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Injury, poisoning and procedural complications	-	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	0,2364
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	-	173	11	6,36	162	93,64	NA	NA	NA	2,16	0,74	6,25	0,1473	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	-	174	5	2,87	169	97,13	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	-	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	-	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	-	163	9	5,52	154	94,48	NA	NA	NA	2,25	0,69	7,32	0,1664	0,9352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	-	173	4	2,31	169	97,69	NA	NA	NA	-	-	-	-	0,9352

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	-	32	2	6,25	30	93,75	NA	NA	NA	2,51	0,23	28,08	0,4383	0,9352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	-	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,9352
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Injury, poisoning and procedural complications	-	18	1	5,56	17	94,44	NA	NA	NA	0,50	0,03	8,46	0,6250	0,3713
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Injury, poisoning and procedural complications	-	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,3713
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Injury, poisoning and procedural complications	-	61	6	9,84	55	90,16	-	-	-	-	-	-	-	0,3713
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Injury, poisoning and procedural complications	-	64	0	0,00	64	100,00	-	-	-	-	-	-	-	0,3713
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Injury, poisoning and procedural complications	-	47	3	6,38	44	93,62	NA	NA	NA	3,28	0,34	32,08	0,2803	0,3713
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Injury, poisoning and procedural complications	-	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,3713
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Injury, poisoning and procedural complications	-	69	1	1,45	68	98,55	NA	NA	NA	0,37	0,04	3,68	0,3774	0,3713
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Injury, poisoning and procedural complications	-	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	0,3713
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Injury, poisoning and procedural complications	-	117	9	7,69	108	92,31	NA	NA	NA	4,90	1,05	22,85	0,0257	0,0968
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Injury, poisoning and procedural complications	-	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	0,0968
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Injury, poisoning and procedural complications	-	78	2	2,56	76	97,44	NA	NA	NA	0,65	0,10	4,01	0,6389	0,0968
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Injury, poisoning and procedural complications	-	68	3	4,41	65	95,59	NA	NA	NA	-	-	-	-	0,0968
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Injury, poisoning and procedural complications	-	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Injury, poisoning and procedural complications	-	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Injury, poisoning and procedural complications	-	161	11	6,83	150	93,17	NA	NA	NA	2,63	0,83	8,34	0,0875	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Injury, poisoning and procedural complications	-	162	4	2,47	158	97,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	-	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	-	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	-	171	10	5,85	161	94,15	NA	NA	NA	2,14	0,73	6,28	0,1562	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	-	185	5	2,70	180	97,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Injury, poisoning and procedural complications	-	48	1	2,08	47	97,92	NA	NA	NA	0,29	0,03	2,79	0,2540	0,0368
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Injury, poisoning and procedural complications	-	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,0368
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Injury, poisoning and procedural complications	-	147	10	6,80	137	93,20	NA	NA	NA	5,30	1,16	24,25	0,0161	0,0368
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Injury, poisoning and procedural complications	-	157	2	1,27	155	98,73	NA	NA	NA	-	-	-	-	0,0368
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Injury, poisoning and procedural complications	-	98	5	5,10	93	94,90	NA	NA	NA	2,44	0,47	12,57	0,2717	0,8833
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Injury, poisoning and procedural complications	-	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	0,8833
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Injury, poisoning and procedural complications	-	97	6	6,19	91	93,81	NA	NA	NA	2,07	0,52	8,34	0,2936	0,8833
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Injury, poisoning and procedural complications	-	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,8833
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Injury, poisoning and procedural complications	-	98	7	7,14	91	92,86	NA	NA	NA	5,14	1,06	24,93	0,0238	0,1955

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Injury, poisoning and procedural complications	-	111	2	1,80	109	98,20	NA	NA	NA	-	-	-	-	0,1955
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Injury, poisoning and procedural complications	-	97	4	4,12	93	95,88	NA	NA	NA	1,22	0,27	5,49	0,7982	0,1955
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Injury, poisoning and procedural complications	-	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,1955
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Injury, poisoning and procedural complications	-	61	2	3,28	59	96,72	NA	NA	NA	0,29	0,03	2,79	0,2540	0,0444
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Injury, poisoning and procedural complications	-	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,0444
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Injury, poisoning and procedural complications	-	134	9	6,72	125	93,28	NA	NA	NA	4,80	1,03	22,25	0,0270	0,0444
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Injury, poisoning and procedural complications	-	142	2	1,41	140	98,59	NA	NA	NA	-	-	-	-	0,0444
Patients with at least one SAE	total	-	SVd Arm	Injury, poisoning and procedural complications	-	195	10	5,13	185	94,87	NA	NA	NA	2,61	0,82	8,36	0,0930	NA
Patients with at least one SAE	total	-	Vd Arm	Injury, poisoning and procedural complications	-	204	4	1,96	200	98,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	Injury, poisoning and procedural complications	-	80	2	2,50	78	97,50	NA	NA	NA	1,00	0,13	7,47	0,9973	0,2888
Patients with at least one SAE	Gender	Female	Vd Arm	Injury, poisoning and procedural complications	-	91	2	2,20	89	97,80	NA	NA	NA	-	-	-	-	0,2888
Patients with at least one SAE	Gender	Male	SVd Arm	Injury, poisoning and procedural complications	-	115	8	6,96	107	93,04	NA	NA	NA	3,95	0,83	18,69	0,0617	0,2888
Patients with at least one SAE	Gender	Male	Vd Arm	Injury, poisoning and procedural complications	-	113	2	1,77	111	98,23	NA	NA	NA	-	-	-	-	0,2888
Patients with at least one SAE	Age Group	<65	SVd Arm	Injury, poisoning and procedural complications	-	86	2	2,33	84	97,67	NA	NA	NA	2,17	0,19	24,27	0,5179	0,7321
Patients with at least one SAE	Age Group	<65	Vd Arm	Injury, poisoning and procedural complications	-	75	1	1,33	74	98,67	NA	NA	NA	-	-	-	-	0,7321
Patients with at least one SAE	Age Group	>=65	SVd Arm	Injury, poisoning and procedural complications	-	109	8	7,34	101	92,66	NA	NA	NA	3,52	0,92	13,42	0,0500	0,7321

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Age Group	>=65	Vd Arm	Injury, poisoning and procedural complications	-	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	0,7321
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	-	173	9	5,20	164	94,80	NA	NA	NA	2,23	0,68	7,31	0,1744	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	-	174	4	2,30	170	97,70	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	-	12	1	8,33	11	91,67	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	-	16	0	0,00	16	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	Injury, poisoning and procedural complications	-	163	7	4,29	156	95,71	NA	NA	NA	2,35	0,61	9,10	0,2038	0,7107
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	Injury, poisoning and procedural complications	-	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	0,7107
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	Injury, poisoning and procedural complications	-	32	3	9,38	29	90,62	NA	NA	NA	3,87	0,40	37,50	0,2087	0,7107
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	Injury, poisoning and procedural complications	-	31	1	3,23	30	96,77	NA	NA	NA	-	-	-	-	0,7107
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	Injury, poisoning and procedural complications	-	18	1	5,56	17	94,44	NA	NA	NA	0,50	0,03	8,46	0,6250	0,5696
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	Injury, poisoning and procedural complications	-	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,5696
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	Injury, poisoning and procedural complications	-	61	4	6,56	57	93,44	-	-	-	-	-	-	-	0,5696
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	Injury, poisoning and procedural complications	-	64	0	0,00	64	100,00	-	-	-	-	-	-	-	0,5696
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	Injury, poisoning and procedural complications	-	47	3	6,38	44	93,62	NA	NA	NA	3,28	0,34	32,08	0,2803	0,5696
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	Injury, poisoning and procedural complications	-	53	1	1,89	52	98,11	NA	NA	NA	-	-	-	-	0,5696
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	Injury, poisoning and procedural complications	-	69	2	2,90	67	97,10	NA	NA	NA	1,03	0,14	7,48	0,9787	0,5696

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	Injury, poisoning and procedural complications	-	70	2	2,86	68	97,14	NA	NA	NA	-	-	-	-	0,5696
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Injury, poisoning and procedural complications	-	117	8	6,84	109	93,16	NA	NA	NA	4,38	0,92	20,83	0,0432	0,2319
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Injury, poisoning and procedural complications	-	136	2	1,47	134	98,53	NA	NA	NA	-	-	-	-	0,2319
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	Injury, poisoning and procedural complications	-	78	2	2,56	76	97,44	NA	NA	NA	0,94	0,13	6,85	0,9491	0,2319
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	Injury, poisoning and procedural complications	-	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,2319
Patients with at least one SAE	Race	Races other than White	SVd Arm	Injury, poisoning and procedural complications	-	34	0	0,00	34	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAE	Race	Races other than White	Vd Arm	Injury, poisoning and procedural complications	-	42	0	0,00	42	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Race	White	SVd Arm	Injury, poisoning and procedural complications	-	161	10	6,21	151	93,79	NA	NA	NA	2,52	0,78	8,14	0,1088	NA
Patients with at least one SAE	Race	White	Vd Arm	Injury, poisoning and procedural complications	-	162	4	2,47	158	97,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	-	6	0	0,00	6	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	-	5	0	0,00	5	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Injury, poisoning and procedural complications	-	171	9	5,26	162	94,74	NA	NA	NA	2,53	0,78	8,25	0,1110	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Injury, poisoning and procedural complications	-	185	4	2,16	181	97,84	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	Injury, poisoning and procedural complications	-	48	1	2,08	47	97,92	NA	NA	NA	0,29	0,03	2,79	0,2540	0,0233
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	Injury, poisoning and procedural complications	-	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,0233

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	Injury, poisoning and procedural complications	-	147	9	6,12	138	93,88	NA	NA	NA	10,10	1,28	79,88	0,0068	0,0233
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	Injury, poisoning and procedural complications	-	157	1	0,64	156	99,36	NA	NA	NA	-	-	-	-	0,0233
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	Injury, poisoning and procedural complications	-	98	5	5,10	93	94,90	NA	NA	NA	5,22	0,61	44,86	0,0924	0,4045
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	Injury, poisoning and procedural complications	-	104	1	0,96	103	99,04	NA	NA	NA	-	-	-	-	0,4045
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	Injury, poisoning and procedural complications	-	97	5	5,15	92	94,85	NA	NA	NA	1,74	0,41	7,32	0,4450	0,4045
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	Injury, poisoning and procedural complications	-	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,4045
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	Injury, poisoning and procedural complications	-	98	7	7,14	91	92,86	NA	NA	NA	10,10	1,24	82,62	0,0079	0,0854
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	Injury, poisoning and procedural complications	-	111	1	0,90	110	99,10	NA	NA	NA	-	-	-	-	0,0854
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	Injury, poisoning and procedural complications	-	97	3	3,09	94	96,91	NA	NA	NA	0,99	0,20	4,96	0,9879	0,0854
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	Injury, poisoning and procedural complications	-	93	3	3,23	90	96,77	NA	NA	NA	-	-	-	-	0,0854
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	Injury, poisoning and procedural complications	-	61	2	3,28	59	96,72	NA	NA	NA	0,29	0,03	2,79	0,2540	0,0283
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	Injury, poisoning and procedural complications	-	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,0283
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	Injury, poisoning and procedural complications	-	134	8	5,97	126	94,03	NA	NA	NA	9,07	1,13	72,76	0,0120	0,0283
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	Injury, poisoning and procedural complications	-	142	1	0,70	141	99,30	NA	NA	NA	-	-	-	-	0,0283
Patients with at least one AE	total	-	SVd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	195	19	9,74	176	90,26	NA	NA	NA	0,63	0,35	1,15	0,1273	NA
Patients with at least one AE	total	-	Vd Arm	Respiratory, thoracic and mediastinal disorders	Dyspnoea	204	28	13,73	176	86,27	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Investigations	-	80	38	47,50	42	52,50	9,92	4,14	NA	2,51	1,42	4,42	0,0010	0,0743
Patients with at least one AE	Gender	Female	Vd Arm	Investigations	-	91	22	24,18	69	75,82	NA	21,65	NA	-	-	-	-	0,0743

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Male	SVd Arm	Investigations	-	115	50	43,48	65	56,52	8,61	6,70	NA	1,32	0,87	2,01	0,1918	0,0743
Patients with at least one AE	Gender	Male	Vd Arm	Investigations	-	113	40	35,40	73	64,60	NA	10,28	NA	-	-	-	-	0,0743
Patients with at least one AE	Age Group	<65	SVd Arm	Investigations	-	86	40	46,51	46	53,49	8,08	5,75	NA	1,33	0,80	2,23	0,2728	0,2777
Patients with at least one AE	Age Group	<65	Vd Arm	Investigations	-	75	25	33,33	50	66,67	NA	10,18	NA	-	-	-	-	0,2777
Patients with at least one AE	Age Group	>=65	SVd Arm	Investigations	-	109	48	44,04	61	55,96	10,38	5,09	NA	1,94	1,25	3,02	0,0029	0,2777
Patients with at least one AE	Age Group	>=65	Vd Arm	Investigations	-	129	37	28,68	92	71,32	NA	21,65	NA	-	-	-	-	0,2777
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Investigations	-	173	79	45,66	94	54,34	10,38	6,24	NA	1,68	1,18	2,40	0,0039	0,8579
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Investigations	-	174	51	29,31	123	70,69	NA	NA	NA	-	-	-	-	0,8579
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Investigations	-	12	7	58,33	5	41,67	3,02	1,64	NA	1,89	0,56	6,37	0,3010	0,8579
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Investigations	-	16	7	43,75	9	56,25	21,65	3,61	NA	-	-	-	-	0,8579
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Investigations	-	163	72	44,17	91	55,83	10,38	6,70	NA	1,65	1,15	2,37	0,0065	0,8695
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Investigations	-	173	50	28,90	123	71,10	NA	NA	NA	-	-	-	-	0,8695
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Investigations	-	32	16	50,00	16	50,00	5,59	2,83	NA	1,53	0,69	3,41	0,2935	0,8695
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Investigations	-	31	12	38,71	19	61,29	21,65	4,27	NA	-	-	-	-	0,8695
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Investigations	-	18	8	44,44	10	55,56	10,38	2,56	NA	1,02	0,27	3,84	0,9769	0,3305
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Investigations	-	17	5	29,41	12	70,59	NA	6,70	NA	-	-	-	-	0,3305
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Investigations	-	61	28	45,90	33	54,10	8,08	3,48	NA	1,57	0,87	2,85	0,1315	0,3305
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Investigations	-	64	21	32,81	43	67,19	NA	15,64	NA	-	-	-	-	0,3305
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Investigations	-	47	12	25,53	35	74,47	NA	NA	NA	1,01	0,44	2,30	0,9820	0,3305
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Investigations	-	53	11	20,75	42	79,25	NA	NA	NA	-	-	-	-	0,3305
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Investigations	-	69	40	57,97	29	42,03	5,59	3,02	NA	2,29	1,36	3,85	0,0013	0,3305
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Investigations	-	70	25	35,71	45	64,29	NA	10,18	NA	-	-	-	-	0,3305
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Investigations	-	117	42	35,90	75	64,10	34,50	10,38	NA	1,24	0,79	1,95	0,3403	0,0529
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Investigations	-	136	38	27,94	98	72,06	NA	NA	NA	-	-	-	-	0,0529
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Investigations	-	78	46	58,97	32	41,03	4,14	2,99	9,92	2,44	1,46	4,10	0,0005	0,0529
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Investigations	-	68	24	35,29	44	64,71	NA	10,18	NA	-	-	-	-	0,0529
Patients with at least one AE	Race	Races other than White	SVd Arm	Investigations	-	34	19	55,88	15	44,12	4,04	1,91	NA	1,59	0,82	3,12	0,1689	0,8211
Patients with at least one AE	Race	Races other than White	Vd Arm	Investigations	-	42	19	45,24	23	54,76	14,39	3,61	NA	-	-	-	-	0,8211
Patients with at least one AE	Race	White	SVd Arm	Investigations	-	161	69	42,86	92	57,14	34,50	7,59	NA	1,74	1,18	2,58	0,0048	0,8211

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	Vd Arm	Investigations	-	162	43	26,54	119	73,46	NA	NA	NA	-	-	-	-	0,8211
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Investigations	-	6	5	83,33	1	16,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Investigations	-	5	3	60,00	2	40,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Investigations	-	171	75	43,86	96	56,14	34,50	6,70	NA	1,60	1,12	2,29	0,0087	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Investigations	-	185	56	30,27	129	69,73	NA	21,65	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Investigations	-	48	21	43,75	27	56,25	43,96	5,09	NA	2,05	0,99	4,25	0,0490	0,5309
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Investigations	-	47	13	27,66	34	72,34	21,65	21,65	NA	-	-	-	-	0,5309
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Investigations	-	147	67	45,58	80	54,42	8,61	5,78	NA	1,58	1,09	2,29	0,0152	0,5309
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Investigations	-	157	49	31,21	108	68,79	NA	15,64	NA	-	-	-	-	0,5309
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Investigations	-	98	49	50,00	49	50,00	6,93	3,48	NA	1,59	1,03	2,45	0,0354	0,7363
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Investigations	-	104	36	34,62	68	65,38	NA	14,39	NA	-	-	-	-	0,7363
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Investigations	-	97	39	40,21	58	59,79	43,96	8,08	NA	1,78	1,07	2,97	0,0245	0,7363
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Investigations	-	100	26	26,00	74	74,00	NA	NA	NA	-	-	-	-	0,7363
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Investigations	-	98	41	41,84	57	58,16	34,50	6,24	NA	1,42	0,91	2,22	0,1235	0,3945
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Investigations	-	111	38	34,23	73	65,77	NA	14,39	NA	-	-	-	-	0,3945
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Investigations	-	97	47	48,45	50	51,55	9,92	4,14	NA	1,90	1,15	3,15	0,0109	0,3945
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Investigations	-	93	24	25,81	69	74,19	NA	21,65	NA	-	-	-	-	0,3945
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Investigations	-	61	29	47,54	32	52,46	6,93	5,09	NA	1,71	0,92	3,17	0,0853	0,8756
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Investigations	-	62	19	30,65	43	69,35	NA	21,65	NA	-	-	-	-	0,8756

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Investigations	-	134	59	44,03	75	55,97	9,92	5,78	NA	1,61	1,08	2,40	0,0176	0,8756
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Investigations	-	142	43	30,28	99	69,72	NA	NA	NA	-	-	-	-	0,8756
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Investigations	-	195	22	11,28	173	88,72	NA	NA	NA	0,97	0,54	1,75	0,9225	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Investigations	-	204	24	11,76	180	88,24	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Investigations	-	80	7	8,75	73	91,25	NA	NA	NA	1,01	0,35	2,90	0,9865	0,9175
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Investigations	-	91	9	9,89	82	90,11	NA	NA	NA	-	-	-	-	0,9175
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Investigations	-	115	15	13,04	100	86,96	NA	NA	NA	0,94	0,46	1,94	0,8736	0,9175
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Investigations	-	113	15	13,27	98	86,73	NA	NA	NA	-	-	-	-	0,9175
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Investigations	-	86	6	6,98	80	93,02	NA	NA	NA	0,58	0,20	1,69	0,3123	0,1740
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Investigations	-	75	9	12,00	66	88,00	NA	NA	NA	-	-	-	-	0,1740
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Investigations	-	109	16	14,68	93	85,32	NA	NA	NA	1,42	0,69	2,94	0,3419	0,1740
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Investigations	-	129	15	11,63	114	88,37	NA	NA	NA	-	-	-	-	0,1740
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Investigations	-	173	22	12,72	151	87,28	NA	NA	NA	1,05	0,57	1,91	0,8826	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Investigations	-	174	21	12,07	153	87,93	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Investigations	-	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Investigations	-	16	3	18,75	13	81,25	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Investigations	-	163	17	10,43	146	89,57	NA	NA	NA	0,94	0,48	1,83	0,8534	0,8283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Investigations	-	173	18	10,40	155	89,60	NA	NA	NA	-	-	-	-	0,8283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Investigations	-	32	5	15,62	27	84,38	NA	NA	NA	0,80	0,22	2,89	0,7334	0,8283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Investigations	-	31	6	19,35	25	80,65	21,65	21,65	NA	-	-	-	-	0,8283
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Investigations	-	18	2	11,11	16	88,89	NA	NA	NA	0,73	0,05	11,70	0,8247	0,1002
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Investigations	-	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,1002
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Investigations	-	61	8	13,11	53	86,89	NA	NA	NA	1,29	0,44	3,75	0,6372	0,1002
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Investigations	-	64	7	10,94	57	89,06	NA	NA	NA	-	-	-	-	0,1002
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Investigations	-	47	1	2,13	46	97,87	NA	NA	NA	0,10	0,01	0,78	0,0071	0,1002
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Investigations	-	53	9	16,98	44	83,02	NA	NA	NA	-	-	-	-	0,1002
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Investigations	-	69	11	15,94	58	84,06	NA	NA	NA	1,73	0,67	4,49	0,2506	0,1002
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Investigations	-	70	7	10,00	63	90,00	NA	NA	NA	-	-	-	-	0,1002
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Investigations	-	117	10	8,55	107	91,45	NA	NA	NA	0,64	0,29	1,41	0,2686	0,1176
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Investigations	-	136	18	13,24	118	86,76	NA	NA	NA	-	-	-	-	0,1176
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Investigations	-	78	12	15,38	66	84,62	NA	NA	NA	1,77	0,66	4,76	0,2538	0,1176
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Investigations	-	68	6	8,82	62	91,18	NA	NA	NA	-	-	-	-	0,1176

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Investigations	-	34	3	8,82	31	91,18	NA	NA	NA	1,10	0,24	5,07	0,8980	0,8330
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Investigations	-	42	4	9,52	38	90,48	NA	NA	NA	-	-	-	-	0,8330
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Investigations	-	161	19	11,80	142	88,20	NA	NA	NA	0,92	0,49	1,76	0,8117	0,8330
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Investigations	-	162	20	12,35	142	87,65	NA	NA	NA	-	-	-	-	0,8330
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Investigations	-	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Investigations	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Investigations	-	171	19	11,11	152	88,89	NA	NA	NA	0,86	0,47	1,59	0,6374	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Investigations	-	185	24	12,97	161	87,03	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Investigations	-	48	4	8,33	44	91,67	NA	NA	NA	2,12	0,38	11,80	0,3816	0,3384
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Investigations	-	47	3	6,38	44	93,62	NA	21,65	NA	-	-	-	-	0,3384
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Investigations	-	147	18	12,24	129	87,76	NA	NA	NA	0,87	0,46	1,63	0,6560	0,3384
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Investigations	-	157	21	13,38	136	86,62	NA	NA	NA	-	-	-	-	0,3384
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Investigations	-	98	10	10,20	88	89,80	NA	NA	NA	0,64	0,29	1,43	0,2731	0,1281
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Investigations	-	104	15	14,42	89	85,58	NA	NA	NA	-	-	-	-	0,1281
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Investigations	-	97	12	12,37	85	87,63	NA	NA	NA	1,63	0,66	4,02	0,2804	0,1281

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Investigations	-	100	9	9,00	91	91,00	NA	NA	NA	-	-	-	-	0,1281
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Investigations	-	98	10	10,20	88	89,80	NA	NA	NA	0,97	0,42	2,25	0,9430	0,8518
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Investigations	-	111	12	10,81	99	89,19	NA	NA	NA	-	-	-	-	0,8518
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Investigations	-	97	12	12,37	85	87,63	NA	NA	NA	0,87	0,38	1,98	0,7335	0,8518
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Investigations	-	93	12	12,90	81	87,10	NA	NA	NA	-	-	-	-	0,8518
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Investigations	-	61	5	8,20	56	91,80	NA	NA	NA	1,58	0,37	6,84	0,5354	0,4730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Investigations	-	62	4	6,45	58	93,55	NA	NA	NA	-	-	-	-	0,4730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Investigations	-	134	17	12,69	117	87,31	NA	NA	NA	0,88	0,46	1,69	0,7014	0,4730
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Investigations	-	142	20	14,08	122	85,92	NA	NA	NA	-	-	-	-	0,4730
Patients with at least one AE	total	-	SVd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	195	11	5,64	184	94,36	NA	NA	NA	3,70	1,03	13,31	0,0323	NA
Patients with at least one AE	total	-	Vd Arm	Respiratory, thoracic and mediastinal disorders	Epistaxis	204	3	1,47	201	98,53	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Metabolism and nutrition disorders	-	80	52	65,00	28	35,00	3,48	2,33	7,66	3,17	1,92	5,23	0,0000	0,3247
Patients with at least one AE	Gender	Female	Vd Arm	Metabolism and nutrition disorders	-	91	27	29,67	64	70,33	NA	13,47	NA	-	-	-	-	0,3247
Patients with at least one AE	Gender	Male	SVd Arm	Metabolism and nutrition disorders	-	115	56	48,70	59	51,30	8,61	3,48	NA	2,25	1,42	3,57	0,0004	0,3247
Patients with at least one AE	Gender	Male	Vd Arm	Metabolism and nutrition disorders	-	113	28	24,78	85	75,22	29,01	24,41	NA	-	-	-	-	0,3247
Patients with at least one AE	Age Group	<65	SVd Arm	Metabolism and nutrition disorders	-	86	44	51,16	42	48,84	7,59	3,15	NA	2,42	1,39	4,22	0,0013	0,6635
Patients with at least one AE	Age Group	<65	Vd Arm	Metabolism and nutrition disorders	-	75	20	26,67	55	73,33	NA	16,46	NA	-	-	-	-	0,6635
Patients with at least one AE	Age Group	>=65	SVd Arm	Metabolism and nutrition disorders	-	109	64	58,72	45	41,28	3,48	2,33	8,87	2,83	1,85	4,31	0,0000	0,6635
Patients with at least one AE	Age Group	>=65	Vd Arm	Metabolism and nutrition disorders	-	129	35	27,13	94	72,87	NA	29,01	NA	-	-	-	-	0,6635
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	-	173	94	54,34	79	45,66	6,01	3,22	12,25	2,60	1,80	3,74	0,0000	0,7073

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	-	174	44	25,29	130	74,71	29,01	24,41	NA	-	-	-	-	0,7073
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	-	12	8	66,67	4	33,33	2,10	0,13	NA	3,41	0,87	13,32	0,0697	0,7073
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	-	16	5	31,25	11	68,75	NA	2,10	NA	-	-	-	-	0,7073
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	-	163	87	53,37	76	46,63	6,44	3,48	NA	2,40	1,67	3,45	0,0000	0,7812
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	-	173	46	26,59	127	73,41	NA	24,41	NA	-	-	-	-	0,7812
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	-	32	21	65,62	11	34,38	2,56	1,22	NA	2,73	1,20	6,22	0,0138	0,7812
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	-	31	9	29,03	22	70,97	NA	NA	NA	-	-	-	-	0,7812
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Metabolism and nutrition disorders	-	18	15	83,33	3	16,67	1,41	0,26	NA	8,12	1,81	36,50	0,0013	0,3551
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Metabolism and nutrition disorders	-	17	3	17,65	14	82,35	NA	NA	NA	-	-	-	-	0,3551
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Metabolism and nutrition disorders	-	61	40	65,57	21	34,43	2,23	1,18	3,94	2,46	1,43	4,25	0,0009	0,3551
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Metabolism and nutrition disorders	-	64	22	34,38	42	65,62	24,41	13,47	NA	-	-	-	-	0,3551
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Metabolism and nutrition disorders	-	47	16	34,04	31	65,96	NA	10,38	NA	1,69	0,74	3,86	0,2087	0,3551
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Metabolism and nutrition disorders	-	53	10	18,87	43	81,13	NA	NA	NA	-	-	-	-	0,3551
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Metabolism and nutrition disorders	-	69	37	53,62	32	46,38	5,59	2,79	NA	2,59	1,48	4,54	0,0006	0,3551
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Metabolism and nutrition disorders	-	70	20	28,57	50	71,43	29,01	21,52	NA	-	-	-	-	0,3551
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Metabolism and nutrition disorders	-	117	62	52,99	55	47,01	6,44	3,15	NA	2,49	1,62	3,83	0,0000	0,8298
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Metabolism and nutrition disorders	-	136	33	24,26	103	75,74	NA	24,41	NA	-	-	-	-	0,8298
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Metabolism and nutrition disorders	-	78	46	58,97	32	41,03	4,27	2,33	12,25	2,69	1,57	4,61	0,0002	0,8298
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Metabolism and nutrition disorders	-	68	22	32,35	46	67,65	29,01	12,91	NA	-	-	-	-	0,8298
Patients with at least one AE	Race	Races other than White	SVd Arm	Metabolism and nutrition disorders	-	34	23	67,65	11	32,35	2,10	1,25	NA	2,32	1,16	4,65	0,0142	0,7865
Patients with at least one AE	Race	Races other than White	Vd Arm	Metabolism and nutrition disorders	-	42	16	38,10	26	61,90	21,52	16,46	NA	-	-	-	-	0,7865
Patients with at least one AE	Race	White	SVd Arm	Metabolism and nutrition disorders	-	161	85	52,80	76	47,20	6,01	3,22	NA	2,59	1,76	3,81	0,0000	0,7865

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Race	White	Vd Arm	Metabolism and nutrition disorders	-	162	39	24,07	123	75,93	NA	29,01	NA	-	-	-	-	0,7865
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	-	6	6	100,00	0	0,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	-	5	2	40,00	3	60,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	-	171	89	52,05	82	47,95	7,59	3,48	NA	2,30	1,61	3,28	0,0000	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	-	185	51	27,57	134	72,43	NA	29,01	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Metabolism and nutrition disorders	-	48	27	56,25	21	43,75	5,59	2,33	NA	2,60	1,32	5,11	0,0041	0,9279
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Metabolism and nutrition disorders	-	47	13	27,66	34	72,34	29,01	29,01	NA	-	-	-	-	0,9279
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Metabolism and nutrition disorders	-	147	81	55,10	66	44,90	4,63	2,79	11,53	2,51	1,72	3,66	0,0000	0,9279
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Metabolism and nutrition disorders	-	157	42	26,75	115	73,25	NA	21,52	NA	-	-	-	-	0,9279
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Metabolism and nutrition disorders	-	98	53	54,08	45	45,92	6,01	2,56	NA	2,46	1,54	3,91	0,0001	0,8669
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Metabolism and nutrition disorders	-	104	28	26,92	76	73,08	NA	16,46	NA	-	-	-	-	0,8669
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Metabolism and nutrition disorders	-	97	55	56,70	42	43,30	4,27	2,73	NA	2,60	1,63	4,15	0,0000	0,8669
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Metabolism and nutrition disorders	-	100	27	27,00	73	73,00	NA	24,41	NA	-	-	-	-	0,8669
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Metabolism and nutrition disorders	-	98	56	57,14	42	42,86	4,90	2,56	12,25	2,36	1,52	3,67	0,0001	0,6502
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Metabolism and nutrition disorders	-	111	33	29,73	78	70,27	24,41	16,46	NA	-	-	-	-	0,6502
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Metabolism and nutrition disorders	-	97	52	53,61	45	46,39	4,73	2,79	NA	2,77	1,65	4,63	0,0001	0,6502
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Metabolism and nutrition disorders	-	93	22	23,66	71	76,34	NA	29,01	NA	-	-	-	-	0,6502
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Metabolism and nutrition disorders	-	61	35	57,38	26	42,62	4,01	2,10	NA	2,82	1,53	5,20	0,0005	0,6694

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Metabolism and nutrition disorders	-	62	16	25,81	46	74,19	NA	29,01	NA	-	-	-	-	0,6694
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Metabolism and nutrition disorders	-	134	73	54,48	61	45,52	4,90	2,99	NA	2,41	1,62	3,57	0,0000	0,6694
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Metabolism and nutrition disorders	-	142	39	27,46	103	72,54	NA	21,52	NA	-	-	-	-	0,6694
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Metabolism and nutrition disorders	-	195	43	22,05	152	77,95	NA	NA	NA	2,83	1,61	4,97	0,0002	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Metabolism and nutrition disorders	-	204	17	8,33	187	91,67	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Metabolism and nutrition disorders	-	80	19	23,75	61	76,25	NA	NA	NA	3,36	1,44	7,87	0,0033	0,6676
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Metabolism and nutrition disorders	-	91	8	8,79	83	91,21	NA	NA	NA	-	-	-	-	0,6676
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Metabolism and nutrition disorders	-	115	24	20,87	91	79,13	NA	NA	NA	2,61	1,21	5,66	0,0117	0,6676
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Metabolism and nutrition disorders	-	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	0,6676
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Metabolism and nutrition disorders	-	86	19	22,09	67	77,91	NA	NA	NA	6,26	1,80	21,78	0,0012	0,1364
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Metabolism and nutrition disorders	-	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,1364
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Metabolism and nutrition disorders	-	109	24	22,02	85	77,98	NA	NA	NA	2,14	1,10	4,16	0,0214	0,1364
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Metabolism and nutrition disorders	-	129	14	10,85	115	89,15	NA	NA	NA	-	-	-	-	0,1364
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	-	173	32	18,50	141	81,50	NA	NA	NA	2,32	1,23	4,36	0,0072	0,2473
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	-	174	14	8,05	160	91,95	NA	NA	NA	-	-	-	-	0,2473
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	-	12	7	58,33	5	41,67	3,48	0,26	NA	6,54	1,27	33,66	0,0130	0,2473

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	-	16	3	18,75	13	81,25	NA	NA	NA	-	-	-	-	0,2473
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Metabolism and nutrition disorders	-	163	31	19,02	132	80,98	NA	NA	NA	2,50	1,31	4,78	0,0042	0,5081
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Metabolism and nutrition disorders	-	173	13	7,51	160	92,49	NA	NA	NA	-	-	-	-	0,5081
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Metabolism and nutrition disorders	-	32	12	37,50	20	62,50	NA	5,91	NA	3,90	1,24	12,27	0,0126	0,5081
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Metabolism and nutrition disorders	-	31	4	12,90	27	87,10	NA	NA	NA	-	-	-	-	0,5081
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Metabolism and nutrition disorders	-	18	8	44,44	10	55,56	27,20	2,56	NA	5,69	0,70	46,50	0,0674	0,2275
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Metabolism and nutrition disorders	-	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,2275
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Metabolism and nutrition disorders	-	61	17	27,87	44	72,13	NA	NA	NA	2,76	1,08	7,02	0,0263	0,2275
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Metabolism and nutrition disorders	-	64	6	9,38	58	90,62	NA	NA	NA	-	-	-	-	0,2275
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Metabolism and nutrition disorders	-	47	4	8,51	43	91,49	NA	NA	NA	0,74	0,20	2,80	0,6562	0,2275
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Metabolism and nutrition disorders	-	53	5	9,43	48	90,57	NA	NA	NA	-	-	-	-	0,2275
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Metabolism and nutrition disorders	-	69	14	20,29	55	79,71	NA	NA	NA	3,62	1,29	10,15	0,0091	0,2275
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Metabolism and nutrition disorders	-	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,2275
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Metabolism and nutrition disorders	-	117	26	22,22	91	77,78	NA	NA	NA	2,33	1,17	4,64	0,0132	0,4855
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Metabolism and nutrition disorders	-	136	12	8,82	124	91,18	NA	NA	NA	-	-	-	-	0,4855
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Metabolism and nutrition disorders	-	78	17	21,79	61	78,21	NA	NA	NA	3,60	1,32	9,84	0,0079	0,4855

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Metabolism and nutrition disorders	-	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,4855
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Metabolism and nutrition disorders	-	34	8	23,53	26	76,47	NA	NA	NA	2,11	0,68	6,59	0,1888	0,4832
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Metabolism and nutrition disorders	-	42	6	14,29	36	85,71	NA	NA	NA	-	-	-	-	0,4832
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Metabolism and nutrition disorders	-	161	35	21,74	126	78,26	NA	NA	NA	3,40	1,71	6,74	0,0002	0,4832
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Metabolism and nutrition disorders	-	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	0,4832
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Metabolism and nutrition disorders	-	171	39	22,81	132	77,19	NA	NA	NA	2,91	1,62	5,25	0,0002	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Metabolism and nutrition disorders	-	185	16	8,65	169	91,35	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Metabolism and nutrition disorders	-	48	8	16,67	40	83,33	NA	NA	NA	4,37	0,92	20,75	0,0436	0,5499
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Metabolism and nutrition disorders	-	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,5499
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Metabolism and nutrition disorders	-	147	35	23,81	112	76,19	NA	NA	NA	2,62	1,43	4,81	0,0013	0,5499
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Metabolism and nutrition disorders	-	157	15	9,55	142	90,45	NA	NA	NA	-	-	-	-	0,5499
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Metabolism and nutrition disorders	-	98	19	19,39	79	80,61	NA	NA	NA	2,01	0,95	4,24	0,0632	0,2025
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Metabolism and nutrition disorders	-	104	11	10,58	93	89,42	NA	NA	NA	-	-	-	-	0,2025

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Metabolism and nutrition disorders	-	97	24	24,74	73	75,26	NA	NA	NA	4,29	1,75	10,51	0,0005	0,2025
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Metabolism and nutrition disorders	-	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,2025
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Metabolism and nutrition disorders	-	98	24	24,49	74	75,51	NA	NA	NA	3,73	1,66	8,35	0,0006	0,3376
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Metabolism and nutrition disorders	-	111	8	7,21	103	92,79	NA	NA	NA	-	-	-	-	0,3376
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Metabolism and nutrition disorders	-	97	19	19,59	78	80,41	NA	NA	NA	2,14	0,96	4,75	0,0559	0,3376
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Metabolism and nutrition disorders	-	93	9	9,68	84	90,32	NA	NA	NA	-	-	-	-	0,3376
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Metabolism and nutrition disorders	-	61	10	16,39	51	83,61	NA	NA	NA	5,11	1,09	23,88	0,0213	0,3933
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Metabolism and nutrition disorders	-	62	2	3,23	60	96,77	NA	NA	NA	-	-	-	-	0,3933
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Metabolism and nutrition disorders	-	134	33	24,63	101	75,37	NA	NA	NA	2,48	1,34	4,60	0,0028	0,3933
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Metabolism and nutrition disorders	-	142	15	10,56	127	89,44	NA	NA	NA	-	-	-	-	0,3933
Patients with at least one AE	total	-	SVd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	195	14	7,18	181	92,82	NA	NA	NA	3,57	1,16	11,04	0,0185	NA
Patients with at least one AE	total	-	Vd Arm	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	204	4	1,96	200	98,04	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Musculoskeletal and connective tissue disorders	-	80	29	36,25	51	63,75	22,57	14,19	NA	0,94	0,54	1,65	0,8364	0,9100
Patients with at least one AE	Gender	Female	Vd Arm	Musculoskeletal and connective tissue disorders	-	91	31	34,07	60	65,93	NA	10,45	NA	-	-	-	-	0,9100
Patients with at least one AE	Gender	Male	SVd Arm	Musculoskeletal and connective tissue disorders	-	115	48	41,74	67	58,26	20,53	10,61	NA	0,98	0,65	1,47	0,9271	0,9100
Patients with at least one AE	Gender	Male	Vd Arm	Musculoskeletal and connective tissue disorders	-	113	49	43,36	64	56,64	10,09	6,47	NA	-	-	-	-	0,9100
Patients with at least one AE	Age Group	<65	SVd Arm	Musculoskeletal and connective tissue disorders	-	86	34	39,53	52	60,47	22,44	14,19	NA	0,62	0,37	1,02	0,0560	0,0169

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Age Group	<65	Vd Arm	Musculoskeletal and connective tissue disorders	-	75	37	49,33	38	50,67	9,56	4,70	NA	-	-	-	-	0,0169
Patients with at least one AE	Age Group	>=65	SVd Arm	Musculoskeletal and connective tissue disorders	-	109	43	39,45	66	60,55	24,15	7,49	NA	1,38	0,90	2,12	0,1423	0,0169
Patients with at least one AE	Age Group	>=65	Vd Arm	Musculoskeletal and connective tissue disorders	-	129	43	33,33	86	66,67	NA	10,68	NA	-	-	-	-	0,0169
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	-	173	69	39,88	104	60,12	22,57	14,19	NA	0,98	0,70	1,38	0,9161	0,6675
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	-	174	69	39,66	105	60,34	14,39	8,31	NA	-	-	-	-	0,6675
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	-	12	6	50,00	6	50,00	3,22	1,64	NA	1,33	0,35	4,98	0,6763	0,6675
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	-	16	4	25,00	12	75,00	NA	7,92	NA	-	-	-	-	0,6675
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Musculoskeletal and connective tissue disorders	-	163	65	39,88	98	60,12	22,44	12,12	37,06	0,94	0,66	1,33	0,7303	0,7325
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Musculoskeletal and connective tissue disorders	-	173	69	39,88	104	60,12	14,39	9,46	NA	-	-	-	-	0,7325
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Musculoskeletal and connective tissue disorders	-	32	12	37,50	20	62,50	NA	3,45	NA	1,10	0,48	2,56	0,8204	0,7325
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Musculoskeletal and connective tissue disorders	-	31	11	35,48	20	64,52	NA	4,21	NA	-	-	-	-	0,7325
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Musculoskeletal and connective tissue disorders	-	18	9	50,00	9	50,00	10,87	3,25	NA	0,36	0,10	1,28	0,1009	0,2128
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Musculoskeletal and connective tissue disorders	-	17	10	58,82	7	41,18	5,72	2,37	NA	-	-	-	-	0,2128
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Musculoskeletal and connective tissue disorders	-	61	32	52,46	29	47,54	6,24	2,69	NA	0,95	0,58	1,55	0,8316	0,2128
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Musculoskeletal and connective tissue disorders	-	64	36	56,25	28	43,75	6,24	2,33	NA	-	-	-	-	0,2128
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Musculoskeletal and connective tissue disorders	-	47	14	29,79	33	70,21	24,15	12,12	NA	0,67	0,31	1,44	0,3066	0,2128

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Musculoskeletal and connective tissue disorders	-	53	17	32,08	36	67,92	NA	10,45	NA	-	-	-	-	0,2128
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Musculoskeletal and connective tissue disorders	-	69	22	31,88	47	68,12	25,17	17,15	NA	1,43	0,74	2,76	0,2844	0,2128
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Musculoskeletal and connective tissue disorders	-	70	17	24,29	53	75,71	NA	NA	NA	-	-	-	-	0,2128
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Musculoskeletal and connective tissue disorders	-	117	49	41,88	68	58,12	20,53	10,87	37,06	0,89	0,60	1,32	0,5781	0,3096
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Musculoskeletal and connective tissue disorders	-	136	59	43,38	77	56,62	10,09	6,70	NA	-	-	-	-	0,3096
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Musculoskeletal and connective tissue disorders	-	78	28	35,90	50	64,10	25,17	17,15	NA	1,29	0,72	2,32	0,3939	0,3096
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Musculoskeletal and connective tissue disorders	-	68	21	30,88	47	69,12	NA	14,39	NA	-	-	-	-	0,3096
Patients with at least one AE	Race	Races other than White	SVd Arm	Musculoskeletal and connective tissue disorders	-	34	12	35,29	22	64,71	25,00	4,17	NA	0,52	0,23	1,17	0,1099	0,0666
Patients with at least one AE	Race	Races other than White	Vd Arm	Musculoskeletal and connective tissue disorders	-	42	25	59,52	17	40,48	8,31	4,83	NA	-	-	-	-	0,0666
Patients with at least one AE	Race	White	SVd Arm	Musculoskeletal and connective tissue disorders	-	161	65	40,37	96	59,63	20,53	12,06	NA	1,20	0,83	1,74	0,3327	0,0666
Patients with at least one AE	Race	White	Vd Arm	Musculoskeletal and connective tissue disorders	-	162	55	33,95	107	66,05	NA	16,49	NA	-	-	-	-	0,0666
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	-	6	3	50,00	3	50,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	-	5	1	20,00	4	80,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Musculoskeletal and connective tissue disorders	-	171	66	38,60	105	61,40	22,57	12,12	NA	1,00	0,71	1,41	0,9877	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Musculoskeletal and connective tissue disorders	-	185	71	38,38	114	61,62	16,49	9,56	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Musculoskeletal and connective tissue disorders	-	48	20	41,67	28	58,33	25,00	10,61	NA	1,35	0,66	2,75	0,4050	0,3656
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Musculoskeletal and connective tissue disorders	-	47	15	31,91	32	68,09	NA	NA	NA	-	-	-	-	0,3656
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Musculoskeletal and connective tissue disorders	-	147	57	38,78	90	61,22	20,53	11,24	NA	0,94	0,65	1,34	0,7164	0,3656
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Musculoskeletal and connective tissue disorders	-	157	65	41,40	92	58,60	10,68	7,92	NA	-	-	-	-	0,3656
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Musculoskeletal and connective tissue disorders	-	98	33	33,67	65	66,33	25,00	14,19	NA	0,87	0,54	1,38	0,5479	0,3806
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Musculoskeletal and connective tissue disorders	-	104	40	38,46	64	61,54	14,39	9,46	NA	-	-	-	-	0,3806
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Musculoskeletal and connective tissue disorders	-	97	44	45,36	53	54,64	17,15	7,49	NA	1,15	0,74	1,79	0,5208	0,3806
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Musculoskeletal and connective tissue disorders	-	100	40	40,00	60	60,00	16,49	7,13	NA	-	-	-	-	0,3806
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Musculoskeletal and connective tissue disorders	-	98	36	36,73	62	63,27	32,16	10,87	NA	0,93	0,59	1,46	0,7484	0,7888
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Musculoskeletal and connective tissue disorders	-	111	47	42,34	64	57,66	14,39	6,47	NA	-	-	-	-	0,7888
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Musculoskeletal and connective tissue disorders	-	97	41	42,27	56	57,73	22,44	12,06	NA	1,01	0,64	1,62	0,9504	0,7888
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Musculoskeletal and connective tissue disorders	-	93	33	35,48	60	64,52	NA	9,46	NA	-	-	-	-	0,7888
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Musculoskeletal and connective tissue disorders	-	61	27	44,26	34	55,74	22,57	5,59	NA	1,43	0,77	2,64	0,2520	0,2129
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Musculoskeletal and connective tissue disorders	-	62	22	35,48	40	64,52	NA	9,56	NA	-	-	-	-	0,2129
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Musculoskeletal and connective tissue disorders	-	134	50	37,31	84	62,69	20,53	12,06	NA	0,90	0,61	1,33	0,5983	0,2129
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Musculoskeletal and connective tissue disorders	-	142	58	40,85	84	59,15	10,68	7,92	NA	-	-	-	-	0,2129

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	total	-	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	195	83	42,56	112	57,44	20,63	7,13	NA	1,34	0,97	1,85	0,0792	NA
Patients with at least one AE	total	-	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	204	68	33,33	136	66,67	NA	16,59	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Nervous system disorders	-	80	49	61,25	31	38,75	5,72	3,55	8,54	0,97	0,65	1,45	0,8832	0,3889
Patients with at least one AE	Gender	Female	Vd Arm	Nervous system disorders	-	91	55	60,44	36	39,56	3,02	2,33	6,97	-	-	-	-	0,3889
Patients with at least one AE	Gender	Male	SVd Arm	Nervous system disorders	-	115	60	52,17	55	47,83	5,42	4,37	18,53	0,77	0,54	1,09	0,1389	0,3889
Patients with at least one AE	Gender	Male	Vd Arm	Nervous system disorders	-	113	72	63,72	41	36,28	3,58	2,56	6,05	-	-	-	-	0,3889
Patients with at least one AE	Age Group	<65	SVd Arm	Nervous system disorders	-	86	45	52,33	41	47,67	7,10	5,09	NA	0,69	0,45	1,06	0,0902	0,2262
Patients with at least one AE	Age Group	<65	Vd Arm	Nervous system disorders	-	75	47	62,67	28	37,33	3,45	2,50	6,77	-	-	-	-	0,2262
Patients with at least one AE	Age Group	>=65	SVd Arm	Nervous system disorders	-	109	64	58,72	45	41,28	5,09	3,71	7,20	0,97	0,69	1,36	0,8577	0,2262
Patients with at least one AE	Age Group	>=65	Vd Arm	Nervous system disorders	-	129	80	62,02	49	37,98	3,58	2,73	7,00	-	-	-	-	0,2262
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	-	173	98	56,65	75	43,35	5,68	4,63	8,54	0,81	0,61	1,06	0,1285	0,1211
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	-	174	111	63,79	63	36,21	3,45	2,73	5,19	-	-	-	-	0,1211
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	-	12	6	50,00	6	50,00	7,10	0,69	NA	3,04	0,58	15,90	0,1699	0,1211
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	-	16	5	31,25	11	68,75	NA	4,37	NA	-	-	-	-	0,1211
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	-	163	97	59,51	66	40,49	5,42	4,17	7,43	0,82	0,62	1,08	0,1621	0,8587
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	-	173	111	64,16	62	35,84	3,02	2,33	5,13	-	-	-	-	0,8587
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	-	32	12	37,50	20	62,50	7,20	4,86	NA	0,89	0,39	2,01	0,7753	0,8587
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	-	31	16	51,61	15	48,39	7,56	3,48	NA	-	-	-	-	0,8587
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	-	18	12	66,67	6	33,33	2,66	0,56	NA	1,34	0,50	3,61	0,5635	0,4620
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	-	17	11	64,71	6	35,29	1,41	0,59	NA	-	-	-	-	0,4620
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	-	61	40	65,57	21	34,43	2,56	1,12	5,55	1,06	0,68	1,64	0,8055	0,4620
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	-	64	45	70,31	19	29,69	2,33	1,77	4,86	-	-	-	-	0,4620
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	-	47	27	57,45	20	42,55	8,08	5,09	NA	0,87	0,50	1,52	0,6298	0,4620
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	-	53	31	58,49	22	41,51	4,86	2,89	NA	-	-	-	-	0,4620

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Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	-	69	30	43,48	39	56,52	13,01	6,24	NA	0,67	0,41	1,09	0,1018	0,4620
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	-	70	40	57,14	30	42,86	5,19	2,99	NA	-	-	-	-	0,4620
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	-	117	71	60,68	46	39,32	5,09	3,71	8,08	0,90	0,65	1,24	0,5141	0,4824
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	-	136	84	61,76	52	38,24	3,25	2,33	6,77	-	-	-	-	0,4824
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	-	78	38	48,72	40	51,28	7,10	4,60	NA	0,74	0,47	1,15	0,1740	0,4824
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	-	68	43	63,24	25	36,76	4,86	2,73	15,01	-	-	-	-	0,4824
Patients with at least one AE	Race	Races other than White	SVd Arm	Nervous system disorders	-	34	18	52,94	16	47,06	4,17	2,63	NA	0,53	0,28	1,02	0,0546	0,1068
Patients with at least one AE	Race	Races other than White	Vd Arm	Nervous system disorders	-	42	35	83,33	7	16,67	1,79	1,41	3,45	-	-	-	-	0,1068
Patients with at least one AE	Race	White	SVd Arm	Nervous system disorders	-	161	91	56,52	70	43,48	5,72	4,86	8,54	0,96	0,71	1,29	0,7863	0,1068
Patients with at least one AE	Race	White	Vd Arm	Nervous system disorders	-	162	92	56,79	70	43,21	4,86	3,15	7,56	-	-	-	-	0,1068
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	-	6	3	50,00	3	50,00	5,72	5,55	NA	0,64	0,09	4,62	0,6540	0,7263
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	-	5	3	60,00	2	40,00	1,77	0,46	NA	-	-	-	-	0,7263
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	-	171	97	56,73	74	43,27	5,42	4,17	7,43	0,91	0,69	1,20	0,5157	0,7263
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	-	185	111	60,00	74	40,00	3,71	2,89	6,44	-	-	-	-	0,7263
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Nervous system disorders	-	48	23	47,92	25	52,08	8,54	5,42	NA	0,49	0,29	0,85	0,0098	0,0326
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Nervous system disorders	-	47	33	70,21	14	29,79	2,73	1,77	4,86	-	-	-	-	0,0326
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Nervous system disorders	-	147	86	58,50	61	41,50	5,32	4,17	7,10	0,97	0,72	1,30	0,8405	0,0326
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Nervous system disorders	-	157	94	59,87	63	40,13	4,37	2,79	7,00	-	-	-	-	0,0326
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	-	98	52	53,06	46	46,94	6,24	4,63	13,83	0,87	0,60	1,28	0,4823	0,7276

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	-	104	57	54,81	47	45,19	4,86	2,99	15,01	-	-	-	-	0,7276
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	-	97	57	58,76	40	41,24	5,32	3,15	13,01	0,79	0,56	1,13	0,2045	0,7276
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	-	100	70	70,00	30	30,00	2,79	2,30	5,19	-	-	-	-	0,7276
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	-	98	50	51,02	48	48,98	7,43	4,60	NA	0,66	0,46	0,96	0,0270	0,0832
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	-	111	75	67,57	36	32,43	3,02	2,50	5,13	-	-	-	-	0,0832
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	-	97	59	60,82	38	39,18	5,32	3,55	7,20	1,06	0,72	1,56	0,7694	0,0832
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	-	93	52	55,91	41	44,09	5,19	2,76	9,20	-	-	-	-	0,0832
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	-	61	35	57,38	26	42,62	5,42	2,66	NA	0,63	0,39	1,03	0,0616	0,2236
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	-	62	44	70,97	18	29,03	2,73	1,48	4,86	-	-	-	-	0,2236
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	-	134	74	55,22	60	44,78	5,72	4,63	13,83	0,91	0,66	1,24	0,5432	0,2236
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	-	142	83	58,45	59	41,55	4,86	3,15	8,18	-	-	-	-	0,2236
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Nervous system disorders	-	195	20	10,26	175	89,74	NA	NA	NA	0,75	0,42	1,34	0,3241	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Nervous system disorders	-	204	27	13,24	177	86,76	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Nervous system disorders	-	80	12	15,00	68	85,00	NA	NA	NA	1,63	0,67	3,93	0,2765	0,0347
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Nervous system disorders	-	91	9	9,89	82	90,11	NA	NA	NA	-	-	-	-	0,0347
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Nervous system disorders	-	115	8	6,96	107	93,04	NA	NA	NA	0,44	0,19	1,01	0,0471	0,0347
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Nervous system disorders	-	113	18	15,93	95	84,07	NA	NA	NA	-	-	-	-	0,0347

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Nervous system disorders	-	86	9	10,47	77	89,53	NA	NA	NA	1,43	0,45	4,48	0,5415	0,2107
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Nervous system disorders	-	75	5	6,67	70	93,33	NA	NA	NA	-	-	-	-	0,2107
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Nervous system disorders	-	109	11	10,09	98	89,91	NA	NA	NA	0,60	0,29	1,25	0,1656	0,2107
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Nervous system disorders	-	129	22	17,05	107	82,95	NA	NA	NA	-	-	-	-	0,2107
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	-	173	18	10,40	155	89,60	NA	NA	NA	0,80	0,43	1,50	0,4890	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	-	174	22	12,64	152	87,36	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	-	12	2	16,67	10	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	-	16	2	12,50	14	87,50	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	-	163	16	9,82	147	90,18	NA	NA	NA	0,82	0,42	1,58	0,5456	0,9828
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	-	173	21	12,14	152	87,86	NA	NA	NA	-	-	-	-	0,9828
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	-	32	4	12,50	28	87,50	NA	24,61	NA	0,83	0,22	3,18	0,7852	0,9828
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	-	31	6	19,35	25	80,65	NA	16,76	NA	-	-	-	-	0,9828
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	-	18	4	22,22	14	77,78	NA	7,72	NA	5,02	0,55	45,96	0,1147	0,2332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	-	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,2332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	-	61	5	8,20	56	91,80	NA	NA	NA	0,39	0,14	1,13	0,0722	0,2332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	-	64	12	18,75	52	81,25	NA	NA	NA	-	-	-	-	0,2332

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	-	47	6	12,77	41	87,23	NA	NA	NA	0,78	0,25	2,47	0,6727	0,2332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	-	53	7	13,21	46	86,79	NA	NA	NA	-	-	-	-	0,2332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	-	69	5	7,25	64	92,75	NA	NA	NA	0,81	0,25	2,59	0,7184	0,2332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	-	70	7	10,00	63	90,00	NA	NA	NA	-	-	-	-	0,2332
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	-	117	14	11,97	103	88,03	NA	NA	NA	0,85	0,41	1,74	0,6589	0,4653
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	-	136	18	13,24	118	86,76	NA	NA	NA	-	-	-	-	0,4653
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	-	78	6	7,69	72	92,31	NA	NA	NA	0,52	0,17	1,58	0,2403	0,4653
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	-	68	9	13,24	59	86,76	NA	NA	NA	-	-	-	-	0,4653
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Nervous system disorders	-	34	5	14,71	29	85,29	NA	24,61	NA	0,77	0,21	2,81	0,6891	0,9193
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Nervous system disorders	-	42	7	16,67	35	83,33	NA	NA	NA	-	-	-	-	0,9193
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Nervous system disorders	-	161	15	9,32	146	90,68	NA	NA	NA	0,71	0,36	1,40	0,3247	0,9193
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Nervous system disorders	-	162	20	12,35	142	87,65	NA	NA	NA	-	-	-	-	0,9193
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	-	171	18	10,53	153	89,47	NA	NA	NA	0,78	0,42	1,43	0,4155	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	-	185	25	13,51	160	86,49	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Nervous system disorders	-	48	4	8,33	44	91,67	NA	NA	NA	0,68	0,19	2,43	0,5533	0,8753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Nervous system disorders	-	47	6	12,77	41	87,23	NA	NA	NA	-	-	-	-	0,8753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Nervous system disorders	-	147	16	10,88	131	89,12	NA	NA	NA	0,77	0,40	1,47	0,4220	0,8753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Nervous system disorders	-	157	21	13,38	136	86,62	NA	NA	NA	-	-	-	-	0,8753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	-	98	8	8,16	90	91,84	NA	NA	NA	0,74	0,30	1,85	0,5206	0,9830
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	-	104	11	10,58	93	89,42	NA	NA	NA	-	-	-	-	0,9830
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	-	97	12	12,37	85	87,63	NA	NA	NA	0,75	0,35	1,59	0,4543	0,9830
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	-	100	16	16,00	84	84,00	NA	NA	NA	-	-	-	-	0,9830
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	-	98	9	9,18	89	90,82	NA	NA	NA	0,56	0,25	1,27	0,1583	0,3818
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	-	111	17	15,32	94	84,68	NA	NA	NA	-	-	-	-	0,3818
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	-	97	11	11,34	86	88,66	NA	NA	NA	0,95	0,40	2,25	0,9068	0,3818
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	-	93	10	10,75	83	89,25	NA	NA	NA	-	-	-	-	0,3818
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	-	61	5	8,20	56	91,80	NA	NA	NA	0,50	0,15	1,62	0,2347	0,4558
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	-	62	9	14,52	53	85,48	NA	NA	NA	-	-	-	-	0,4558
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	-	134	15	11,19	119	88,81	NA	NA	NA	0,83	0,42	1,66	0,6036	0,4558

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	-	142	18	12,68	124	87,32	NA	NA	NA	-	-	-	-	0,4558
Patients with at least one SAE	total	-	SVd Arm	Nervous system disorders	-	195	8	4,10	187	95,90	NA	NA	NA	0,81	0,32	2,05	0,6549	NA
Patients with at least one SAE	total	-	Vd Arm	Nervous system disorders	-	204	10	4,90	194	95,10	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	Nervous system disorders	-	80	6	7,50	74	92,50	NA	NA	NA	7,18	0,86	60,04	0,0342	0,0064
Patients with at least one SAE	Gender	Female	Vd Arm	Nervous system disorders	-	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,0064
Patients with at least one SAE	Gender	Male	SVd Arm	Nervous system disorders	-	115	2	1,74	113	98,26	NA	NA	NA	0,19	0,04	0,87	0,0168	0,0064
Patients with at least one SAE	Gender	Male	Vd Arm	Nervous system disorders	-	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	0,0064
Patients with at least one SAE	Age Group	<65	SVd Arm	Nervous system disorders	-	86	1	1,16	85	98,84	NA	NA	NA	0,25	0,02	2,48	0,2029	0,1614
Patients with at least one SAE	Age Group	<65	Vd Arm	Nervous system disorders	-	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,1614
Patients with at least one SAE	Age Group	>=65	SVd Arm	Nervous system disorders	-	109	7	6,42	102	93,58	NA	NA	NA	1,52	0,52	4,39	0,4397	0,1614
Patients with at least one SAE	Age Group	>=65	Vd Arm	Nervous system disorders	-	129	7	5,43	122	94,57	NA	NA	NA	-	-	-	-	0,1614
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	Nervous system disorders	-	173	8	4,62	165	95,38	NA	NA	NA	0,89	0,34	2,31	0,8054	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	Nervous system disorders	-	174	9	5,17	165	94,83	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	Nervous system disorders	-	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	Nervous system disorders	-	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	Nervous system disorders	-	163	7	4,29	156	95,71	NA	NA	NA	0,76	0,29	2,00	0,5740	NA
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	Nervous system disorders	-	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	Nervous system disorders	-	32	1	3,12	31	96,88	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	Nervous system disorders	-	31	0	0,00	31	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	Nervous system disorders	-	18	2	11,11	16	88,89	NA	NA	NA	2,33	0,21	26,25	0,4825	0,5603
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	Nervous system disorders	-	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,5603
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	Nervous system disorders	-	61	3	4,92	58	95,08	NA	NA	NA	0,66	0,15	2,98	0,5882	0,5603
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	Nervous system disorders	-	64	5	7,81	59	92,19	NA	NA	NA	-	-	-	-	0,5603
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	Nervous system disorders	-	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,5603

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	Nervous system disorders	-	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,5603
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	Nervous system disorders	-	69	2	2,90	67	97,10	NA	NA	NA	0,47	0,09	2,56	0,3697	0,5603
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	Nervous system disorders	-	70	4	5,71	66	94,29	NA	NA	NA	-	-	-	-	0,5603
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Nervous system disorders	-	117	6	5,13	111	94,87	NA	NA	NA	1,67	0,46	6,03	0,4270	0,0945
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Nervous system disorders	-	136	4	2,94	132	97,06	NA	NA	NA	-	-	-	-	0,0945
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	Nervous system disorders	-	78	2	2,56	76	97,44	NA	NA	NA	0,29	0,06	1,44	0,1074	0,0945
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	Nervous system disorders	-	68	6	8,82	62	91,18	NA	NA	NA	-	-	-	-	0,0945
Patients with at least one SAE	Race	Races other than White	SVd Arm	Nervous system disorders	-	34	0	0,00	34	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Race	Races other than White	Vd Arm	Nervous system disorders	-	42	4	9,52	38	90,48	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Race	White	SVd Arm	Nervous system disorders	-	161	8	4,97	153	95,03	NA	NA	NA	1,55	0,53	4,55	0,4238	NA
Patients with at least one SAE	Race	White	Vd Arm	Nervous system disorders	-	162	6	3,70	156	96,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Nervous system disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Nervous system disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Nervous system disorders	-	171	6	3,51	165	96,49	NA	NA	NA	0,96	0,32	2,86	0,9375	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Nervous system disorders	-	185	7	3,78	178	96,22	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	Nervous system disorders	-	48	3	6,25	45	93,75	NA	NA	NA	1,58	0,26	9,50	0,6113	0,3847
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	Nervous system disorders	-	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,3847
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	Nervous system disorders	-	147	5	3,40	142	96,60	NA	NA	NA	0,62	0,20	1,90	0,4000	0,3847
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	Nervous system disorders	-	157	8	5,10	149	94,90	NA	NA	NA	-	-	-	-	0,3847

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	Nervous system disorders	-	98	3	3,06	95	96,94	NA	NA	NA	1,09	0,22	5,42	0,9164	0,6560
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	Nervous system disorders	-	104	3	2,88	101	97,12	NA	NA	NA	-	-	-	-	0,6560
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	Nervous system disorders	-	97	5	5,15	92	94,85	NA	NA	NA	0,70	0,22	2,20	0,5343	0,6560
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	Nervous system disorders	-	100	7	7,00	93	93,00	NA	NA	NA	-	-	-	-	0,6560
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	Nervous system disorders	-	98	5	5,10	93	94,90	NA	NA	NA	1,02	0,30	3,55	0,9712	0,4864
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	Nervous system disorders	-	111	5	4,50	106	95,50	NA	NA	NA	-	-	-	-	0,4864
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	Nervous system disorders	-	97	3	3,09	94	96,91	NA	NA	NA	0,52	0,12	2,20	0,3664	0,4864
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	Nervous system disorders	-	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,4864
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	Nervous system disorders	-	61	4	6,56	57	93,44	NA	NA	NA	0,86	0,19	3,86	0,8426	0,7634
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	Nervous system disorders	-	62	4	6,45	58	93,55	NA	NA	NA	-	-	-	-	0,7634
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	Nervous system disorders	-	134	4	2,99	130	97,01	NA	NA	NA	0,64	0,18	2,26	0,4791	0,7634
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	Nervous system disorders	-	142	6	4,23	136	95,77	NA	NA	NA	-	-	-	-	0,7634
Patients with at least one AE	total	-	SVd Arm	Skin and subcutaneous tissue disorders	Rash	195	6	3,08	189	96,92	NA	NA	NA	0,66	0,24	1,82	0,4171	NA
Patients with at least one AE	total	-	Vd Arm	Skin and subcutaneous tissue disorders	Rash	204	11	5,39	193	94,61	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Psychiatric disorders	-	80	23	28,75	57	71,25	NA	15,01	NA	1,49	0,78	2,86	0,2275	0,7440
Patients with at least one AE	Gender	Female	Vd Arm	Psychiatric disorders	-	91	17	18,68	74	81,32	NA	27,86	NA	-	-	-	-	0,7440
Patients with at least one AE	Gender	Male	SVd Arm	Psychiatric disorders	-	115	33	28,70	82	71,30	NA	24,94	NA	1,30	0,77	2,19	0,3268	0,7440
Patients with at least one AE	Gender	Male	Vd Arm	Psychiatric disorders	-	113	26	23,01	87	76,99	NA	NA	NA	-	-	-	-	0,7440
Patients with at least one AE	Age Group	<65	SVd Arm	Psychiatric disorders	-	86	17	19,77	69	80,23	NA	NA	NA	0,64	0,33	1,23	0,1755	0,0071
Patients with at least one AE	Age Group	<65	Vd Arm	Psychiatric disorders	-	75	20	26,67	55	73,33	NA	27,86	NA	-	-	-	-	0,0071
Patients with at least one AE	Age Group	>=65	SVd Arm	Psychiatric disorders	-	109	39	35,78	70	64,22	24,94	12,68	NA	2,02	1,20	3,41	0,0072	0,0071
Patients with at least one AE	Age Group	>=65	Vd Arm	Psychiatric disorders	-	129	23	17,83	106	82,17	NA	NA	NA	-	-	-	-	0,0071
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Psychiatric disorders	-	173	53	30,64	120	69,36	NA	NA	NA	1,42	0,93	2,18	0,1031	NA
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Psychiatric disorders	-	174	37	21,26	137	78,74	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Psychiatric disorders	-	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Psychiatric disorders	-	16	3	18,75	13	81,25	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Psychiatric disorders	-	163	52	31,90	111	68,10	NA	24,94	NA	1,44	0,94	2,20	0,0941	0,2319
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Psychiatric disorders	-	173	37	21,39	136	78,61	NA	NA	NA	-	-	-	-	0,2319
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Psychiatric disorders	-	32	4	12,50	28	87,50	NA	NA	NA	0,63	0,18	2,26	0,4774	0,2319
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Psychiatric disorders	-	31	6	19,35	25	80,65	NA	NA	NA	-	-	-	-	0,2319
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Psychiatric disorders	-	18	8	44,44	10	55,56	9,13	1,18	NA	1,12	0,35	3,58	0,8545	0,5807
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Psychiatric disorders	-	17	7	41,18	10	58,82	NA	0,72	NA	-	-	-	-	0,5807
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Psychiatric disorders	-	61	32	52,46	29	47,54	2,96	1,68	NA	1,72	0,99	3,00	0,0534	0,5807
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Psychiatric disorders	-	64	21	32,81	43	67,19	NA	NA	NA	-	-	-	-	0,5807
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Psychiatric disorders	-	47	6	12,77	41	87,23	NA	NA	NA	1,30	0,37	4,50	0,6793	0,5807
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Psychiatric disorders	-	53	5	9,43	48	90,57	NA	27,86	NA	-	-	-	-	0,5807
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Psychiatric disorders	-	69	10	14,49	59	85,51	NA	NA	NA	0,83	0,33	2,05	0,6800	0,5807
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Psychiatric disorders	-	70	10	14,29	60	85,71	NA	NA	NA	-	-	-	-	0,5807
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Psychiatric disorders	-	117	35	29,91	82	70,09	NA	NA	NA	1,30	0,79	2,13	0,3025	0,9077
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Psychiatric disorders	-	136	30	22,06	106	77,94	NA	NA	NA	-	-	-	-	0,9077
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Psychiatric disorders	-	78	21	26,92	57	73,08	NA	24,94	NA	1,36	0,68	2,75	0,3831	0,9077
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Psychiatric disorders	-	68	13	19,12	55	80,88	NA	NA	NA	-	-	-	-	0,9077
Patients with at least one AE	Race	Races other than White	SVd Arm	Psychiatric disorders	-	34	8	23,53	26	76,47	NA	24,94	NA	0,51	0,19	1,41	0,1905	0,0526
Patients with at least one AE	Race	Races other than White	Vd Arm	Psychiatric disorders	-	42	12	28,57	30	71,43	NA	NA	NA	-	-	-	-	0,0526
Patients with at least one AE	Race	White	SVd Arm	Psychiatric disorders	-	161	48	29,81	113	70,19	NA	NA	NA	1,54	0,98	2,43	0,0613	0,0526
Patients with at least one AE	Race	White	Vd Arm	Psychiatric disorders	-	162	31	19,14	131	80,86	NA	NA	NA	-	-	-	-	0,0526
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Psychiatric disorders	-	6	0	0,00	6	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Psychiatric disorders	-	5	2	40,00	3	60,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Psychiatric disorders	-	171	47	27,49	124	72,51	NA	NA	NA	1,23	0,80	1,89	0,3396	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Psychiatric disorders	-	185	39	21,08	146	78,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Psychiatric disorders	-	48	15	31,25	33	68,75	NA	15,01	NA	1,47	0,64	3,38	0,3657	0,7448
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Psychiatric disorders	-	47	9	19,15	38	80,85	NA	NA	NA	-	-	-	-	0,7448
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Psychiatric disorders	-	147	41	27,89	106	72,11	NA	NA	NA	1,25	0,79	1,98	0,3346	0,7448
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Psychiatric disorders	-	157	34	21,66	123	78,34	NA	NA	NA	-	-	-	-	0,7448
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Psychiatric disorders	-	98	27	27,55	71	72,45	NA	24,94	NA	1,54	0,84	2,81	0,1552	0,4504
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Psychiatric disorders	-	104	18	17,31	86	82,69	NA	NA	NA	-	-	-	-	0,4504
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Psychiatric disorders	-	97	29	29,90	68	70,10	NA	NA	NA	1,13	0,66	1,94	0,6561	0,4504
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Psychiatric disorders	-	100	25	25,00	75	75,00	NA	27,86	NA	-	-	-	-	0,4504
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Psychiatric disorders	-	98	27	27,55	71	72,45	NA	24,94	NA	1,07	0,61	1,85	0,8174	0,4051
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Psychiatric disorders	-	111	26	23,42	85	76,58	NA	NA	NA	-	-	-	-	0,4051
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Psychiatric disorders	-	97	29	29,90	68	70,10	NA	NA	NA	1,51	0,82	2,77	0,1787	0,4051
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Psychiatric disorders	-	93	17	18,28	76	81,72	NA	27,86	NA	-	-	-	-	0,4051
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Psychiatric disorders	-	61	18	29,51	43	70,49	NA	15,01	NA	1,91	0,85	4,30	0,1121	0,2819
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Psychiatric disorders	-	62	10	16,13	52	83,87	NA	NA	NA	-	-	-	-	0,2819
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Psychiatric disorders	-	134	38	28,36	96	71,64	NA	24,94	NA	1,14	0,71	1,83	0,5803	0,2819
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Psychiatric disorders	-	142	33	23,24	109	76,76	NA	NA	NA	-	-	-	-	0,2819
Patients with at least one AE	total	-	SVd Arm	Skin and subcutaneous tissue disorders	-	195	46	23,59	149	76,41	32,43	20,07	NA	1,65	1,04	2,60	0,0302	NA
Patients with at least one AE	total	-	Vd Arm	Skin and subcutaneous tissue disorders	-	204	32	15,69	172	84,31	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Gender	Female	SVd Arm	Renal and urinary disorders	-	80	10	12,50	70	87,50	NA	29,50	NA	1,72	0,59	4,99	0,3148	0,9974
Patients with at least one AE	Gender	Female	Vd Arm	Renal and urinary disorders	-	91	8	8,79	83	91,21	NA	NA	NA	-	-	-	-	0,9974
Patients with at least one AE	Gender	Male	SVd Arm	Renal and urinary disorders	-	115	16	13,91	99	86,09	NA	NA	NA	1,71	0,77	3,80	0,1803	0,9974
Patients with at least one AE	Gender	Male	Vd Arm	Renal and urinary disorders	-	113	10	8,85	103	91,15	NA	NA	NA	-	-	-	-	0,9974
Patients with at least one AE	Age Group	<65	SVd Arm	Renal and urinary disorders	-	86	15	17,44	71	82,56	NA	NA	NA	2,15	0,86	5,39	0,0963	0,3039
Patients with at least one AE	Age Group	<65	Vd Arm	Renal and urinary disorders	-	75	7	9,33	68	90,67	NA	NA	NA	-	-	-	-	0,3039
Patients with at least one AE	Age Group	>=65	SVd Arm	Renal and urinary disorders	-	109	11	10,09	98	89,91	NA	NA	NA	1,11	0,48	2,60	0,8036	0,3039
Patients with at least one AE	Age Group	>=65	Vd Arm	Renal and urinary disorders	-	129	11	8,53	118	91,47	NA	NA	NA	-	-	-	-	0,3039
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Renal and urinary disorders	-	173	24	13,87	149	86,13	NA	NA	NA	1,60	0,83	3,08	0,1589	0,2189
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Renal and urinary disorders	-	174	15	8,62	159	91,38	NA	NA	NA	-	-	-	-	0,2189
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Renal and urinary disorders	-	12	1	8,33	11	91,67	NA	NA	NA	0,31	0,02	3,88	0,3454	0,2189
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Renal and urinary disorders	-	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,2189
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Renal and urinary disorders	-	163	20	12,27	143	87,73	NA	NA	NA	1,45	0,72	2,94	0,2969	0,7254
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Renal and urinary disorders	-	173	14	8,09	159	91,91	NA	NA	NA	-	-	-	-	0,7254
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Renal and urinary disorders	-	32	6	18,75	26	81,25	NA	NA	NA	1,90	0,51	7,04	0,3319	0,7254
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Renal and urinary disorders	-	31	4	12,90	27	87,10	NA	NA	NA	-	-	-	-	0,7254
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Renal and urinary disorders	-	18	4	22,22	14	77,78	-	-	-	-	-	-	-	0,1053
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Renal and urinary disorders	-	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,1053
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Renal and urinary disorders	-	61	6	9,84	55	90,16	NA	18,86	NA	0,51	0,17	1,53	0,2198	0,1053
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Renal and urinary disorders	-	64	9	14,06	55	85,94	NA	NA	NA	-	-	-	-	0,1053
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Renal and urinary disorders	-	47	5	10,64	42	89,36	NA	NA	NA	1,25	0,32	4,81	0,7479	0,1053
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Renal and urinary disorders	-	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,1053
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Renal and urinary disorders	-	69	11	15,94	58	84,06	NA	NA	NA	2,84	0,90	8,97	0,0626	0,1053
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Renal and urinary disorders	-	70	4	5,71	66	94,29	NA	NA	NA	-	-	-	-	0,1053

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Renal and urinary disorders	-	117	14	11,97	103	88,03	NA	NA	NA	1,13	0,52	2,44	0,7633	0,3861
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Renal and urinary disorders	-	136	13	9,56	123	90,44	NA	NA	NA	-	-	-	-	0,3861
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Renal and urinary disorders	-	78	12	15,38	66	84,62	NA	NA	NA	2,01	0,70	5,75	0,1868	0,3861
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Renal and urinary disorders	-	68	5	7,35	63	92,65	NA	NA	NA	-	-	-	-	0,3861
Patients with at least one AE	Race	Races other than White	SVd Arm	Renal and urinary disorders	-	34	6	17,65	28	82,35	NA	16,72	NA	1,08	0,30	3,93	0,9019	0,6137
Patients with at least one AE	Race	Races other than White	Vd Arm	Renal and urinary disorders	-	42	6	14,29	36	85,71	NA	NA	NA	-	-	-	-	0,6137
Patients with at least one AE	Race	White	SVd Arm	Renal and urinary disorders	-	161	20	12,42	141	87,58	NA	NA	NA	1,59	0,77	3,28	0,2094	0,6137
Patients with at least one AE	Race	White	Vd Arm	Renal and urinary disorders	-	162	12	7,41	150	92,59	NA	NA	NA	-	-	-	-	0,6137
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Renal and urinary disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Renal and urinary disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Renal and urinary disorders	-	171	23	13,45	148	86,55	NA	NA	NA	1,74	0,90	3,38	0,0963	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Renal and urinary disorders	-	185	15	8,11	170	91,89	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Renal and urinary disorders	-	48	6	12,50	42	87,50	NA	NA	NA	1,99	0,49	8,06	0,3287	0,6821
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Renal and urinary disorders	-	47	3	6,38	44	93,62	NA	NA	NA	-	-	-	-	0,6821
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Renal and urinary disorders	-	147	20	13,61	127	86,39	NA	NA	NA	1,43	0,73	2,83	0,2954	0,6821
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Renal and urinary disorders	-	157	15	9,55	142	90,45	NA	NA	NA	-	-	-	-	0,6821
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Renal and urinary disorders	-	98	14	14,29	84	85,71	NA	29,50	NA	1,38	0,62	3,07	0,4295	0,6997
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Renal and urinary disorders	-	104	11	10,58	93	89,42	NA	NA	NA	-	-	-	-	0,6997
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Renal and urinary disorders	-	97	12	12,37	85	87,63	NA	NA	NA	1,76	0,68	4,52	0,2353	0,6997

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Renal and urinary disorders	-	100	7	7,00	93	93,00	NA	NA	NA	-	-	-	-	0,6997
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Renal and urinary disorders	-	98	17	17,35	81	82,65	NA	NA	NA	1,77	0,83	3,77	0,1336	0,8716
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Renal and urinary disorders	-	111	12	10,81	99	89,19	NA	NA	NA	-	-	-	-	0,8716
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Renal and urinary disorders	-	97	9	9,28	88	90,72	NA	NA	NA	1,58	0,52	4,84	0,4161	0,8716
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Renal and urinary disorders	-	93	6	6,45	87	93,55	NA	NA	NA	-	-	-	-	0,8716
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Renal and urinary disorders	-	61	10	16,39	51	83,61	NA	NA	NA	1,60	0,56	4,53	0,3770	0,9505
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Renal and urinary disorders	-	62	6	9,68	56	90,32	NA	NA	NA	-	-	-	-	0,9505
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Renal and urinary disorders	-	134	16	11,94	118	88,06	NA	NA	NA	1,53	0,71	3,32	0,2771	0,9505
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Renal and urinary disorders	-	142	12	8,45	130	91,55	NA	NA	NA	-	-	-	-	0,9505
Patients with at least one AE	total	-	SVd Arm	Vascular disorders	Hypertension	195	17	8,72	178	91,28	NA	NA	NA	1,11	0,56	2,21	0,7612	NA
Patients with at least one AE	total	-	Vd Arm	Vascular disorders	Hypertension	204	16	7,84	188	92,16	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	80	34	42,50	46	57,50	22,28	5,09	NA	2,04	1,15	3,60	0,0127	0,0475
Patients with at least one AE	Gender	Female	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	91	22	24,18	69	75,82	NA	16,59	NA	-	-	-	-	0,0475
Patients with at least one AE	Gender	Male	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	115	49	42,61	66	57,39	32,00	6,90	NA	1,00	0,67	1,51	0,9872	0,0475
Patients with at least one AE	Gender	Male	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	113	46	40,71	67	59,29	17,77	7,10	NA	-	-	-	-	0,0475
Patients with at least one AE	Age Group	<65	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	86	39	45,35	47	54,65	22,28	6,01	NA	1,16	0,69	1,93	0,5823	0,4898
Patients with at least one AE	Age Group	<65	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	75	28	37,33	47	62,67	17,77	9,49	NA	-	-	-	-	0,4898
Patients with at least one AE	Age Group	>=65	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	109	44	40,37	65	59,63	20,63	6,90	NA	1,46	0,95	2,26	0,0833	0,4898
Patients with at least one AE	Age Group	>=65	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	129	40	31,01	89	68,99	NA	16,59	NA	-	-	-	-	0,4898
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	173	75	43,35	98	56,65	22,28	7,26	NA	1,38	0,97	1,95	0,0717	0,9836
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	174	58	33,33	116	66,67	28,88	16,59	NA	-	-	-	-	0,9836

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	12	6	50,00	6	50,00	3,94	2,14	NA	1,36	0,34	5,40	0,6655	0,9836
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	16	4	25,00	12	75,00	NA	NA	NA	-	-	-	-	0,9836
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	163	70	42,94	93	57,06	20,63	7,13	NA	1,27	0,90	1,79	0,1764	0,3687
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	173	62	35,84	111	64,16	28,88	12,22	NA	-	-	-	-	0,3687
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	32	13	40,62	19	59,38	37,32	6,80	NA	2,09	0,75	5,86	0,1537	0,3687
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	31	6	19,35	25	80,65	NA	NA	NA	-	-	-	-	0,3687
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	18	11	61,11	7	38,89	2,37	1,71	NA	1,20	0,44	3,27	0,7169	0,5909
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	17	8	47,06	9	52,94	4,30	2,07	NA	-	-	-	-	0,5909
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	61	33	54,10	28	45,90	4,90	3,15	NA	1,33	0,80	2,22	0,2765	0,5909
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	64	28	43,75	36	56,25	12,22	3,75	NA	-	-	-	-	0,5909
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	47	9	19,15	38	80,85	NA	NA	NA	2,62	0,80	8,63	0,0998	0,5909
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,5909
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	69	30	43,48	39	56,52	20,63	9,56	NA	1,06	0,62	1,80	0,8279	0,5909
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	70	28	40,00	42	60,00	17,77	11,17	NA	-	-	-	-	0,5909
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	117	44	37,61	73	62,39	32,00	6,80	NA	1,37	0,88	2,14	0,1597	0,5268
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	136	36	26,47	100	73,53	NA	28,88	NA	-	-	-	-	0,5268
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	78	39	50,00	39	50,00	10,55	3,71	NA	1,11	0,69	1,79	0,6596	0,5268
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	68	32	47,06	36	52,94	12,22	4,47	NA	-	-	-	-	0,5268
Patients with at least one AE	Race	Races other than White	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	34	21	61,76	13	38,24	3,94	1,38	NA	1,00	0,55	1,82	0,9897	0,2476
Patients with at least one AE	Race	Races other than White	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	42	26	61,90	16	38,10	3,38	1,71	NA	-	-	-	-	0,2476
Patients with at least one AE	Race	White	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	161	62	38,51	99	61,49	32,00	9,92	NA	1,52	1,02	2,28	0,0377	0,2476
Patients with at least one AE	Race	White	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	162	42	25,93	120	74,07	NA	28,88	NA	-	-	-	-	0,2476

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	6	2	33,33	4	66,67	NA	5,09	NA	0,58	0,04	9,30	0,6949	0,5294
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	5	2	40,00	3	60,00	NA	2,07	NA	-	-	-	-	0,5294
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	171	74	43,27	97	56,73	22,28	6,90	NA	1,42	1,00	2,01	0,0472	0,5294
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	185	60	32,43	125	67,57	NA	16,59	NA	-	-	-	-	0,5294
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	48	18	37,50	30	62,50	37,32	22,28	NA	1,70	0,78	3,68	0,1751	0,5032
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	47	11	23,40	36	76,60	NA	16,59	NA	-	-	-	-	0,5032
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	147	65	44,22	82	55,78	9,92	6,80	NA	1,27	0,89	1,82	0,1935	0,5032
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	157	57	36,31	100	63,69	28,88	12,22	NA	-	-	-	-	0,5032
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	98	40	40,82	58	59,18	32,00	7,13	NA	1,28	0,81	2,02	0,2897	0,7918
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	104	35	33,65	69	66,35	28,88	9,72	NA	-	-	-	-	0,7918
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	97	43	44,33	54	55,67	20,63	5,39	NA	1,40	0,88	2,22	0,1543	0,7918
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	100	33	33,00	67	67,00	NA	12,25	NA	-	-	-	-	0,7918
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	98	39	39,80	59	60,20	32,00	7,13	NA	1,31	0,82	2,10	0,2520	0,8110
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	111	36	32,43	75	67,57	28,88	12,25	NA	-	-	-	-	0,8110
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	97	44	45,36	53	54,64	9,92	4,30	NA	1,21	0,76	1,92	0,4118	0,8110
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	93	32	34,41	61	65,59	NA	16,59	NA	-	-	-	-	0,8110
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	61	22	36,07	39	63,93	37,32	22,28	NA	1,64	0,83	3,24	0,1515	0,5454
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	62	15	24,19	47	75,81	NA	16,59	NA	-	-	-	-	0,5454

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	134	61	45,52	73	54,48	9,92	6,47	NA	1,29	0,89	1,87	0,1820	0,5454
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	142	53	37,32	89	62,68	28,88	12,22	NA	-	-	-	-	0,5454
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	195	12	6,15	183	93,85	NA	NA	NA	1,17	0,52	2,64	0,7103	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	204	12	5,88	192	94,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	80	3	3,75	77	96,25	NA	NA	NA	1,75	0,28	10,70	0,5424	0,5789
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	91	3	3,30	88	96,70	NA	NA	NA	-	-	-	-	0,5789
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	115	9	7,83	106	92,17	NA	NA	NA	0,98	0,39	2,48	0,9665	0,5789
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	113	9	7,96	104	92,04	NA	NA	NA	-	-	-	-	0,5789
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	86	4	4,65	82	95,35	NA	NA	NA	0,75	0,18	3,12	0,6951	0,4964
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	75	4	5,33	71	94,67	NA	NA	NA	-	-	-	-	0,4964
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	109	8	7,34	101	92,66	NA	NA	NA	1,38	0,51	3,72	0,5288	0,4964
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	129	8	6,20	121	93,80	NA	NA	NA	-	-	-	-	0,4964
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	173	12	6,94	161	93,06	NA	NA	NA	1,38	0,59	3,24	0,4614	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	174	10	5,75	164	94,25	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	16	2	12,50	14	87,50	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	163	10	6,13	153	93,87	NA	NA	NA	1,27	0,51	3,17	0,6034	0,3929
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	173	10	5,78	163	94,22	NA	NA	NA	-	-	-	-	0,3929
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	32	2	6,25	30	93,75	NA	NA	NA	0,41	0,04	4,69	0,4593	0,3929
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,3929
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	18	2	11,11	16	88,89	-	-	-	-	-	-	-	0,2555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,2555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	61	5	8,20	56	91,80	NA	NA	NA	1,78	0,42	7,48	0,4233	0,2555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	64	3	4,69	61	95,31	NA	NA	NA	-	-	-	-	0,2555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,2555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,2555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	69	4	5,80	65	94,20	NA	NA	NA	0,60	0,18	2,02	0,4038	0,2555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	70	8	11,43	62	88,57	NA	NA	NA	-	-	-	-	0,2555
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	117	6	5,13	111	94,87	NA	NA	NA	1,32	0,39	4,47	0,6556	0,6224
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	136	5	3,68	131	96,32	NA	NA	NA	-	-	-	-	0,6224
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	78	6	7,69	72	92,31	NA	NA	NA	0,87	0,28	2,66	0,8075	0,6224
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	68	7	10,29	61	89,71	NA	NA	NA	-	-	-	-	0,6224

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	34	3	8,82	31	91,18	NA	NA	NA	1,28	0,27	5,98	0,7547	0,9668
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	42	5	11,90	37	88,10	NA	NA	NA	-	-	-	-	0,9668
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	161	9	5,59	152	94,41	NA	NA	NA	1,23	0,46	3,32	0,6827	0,9668
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	162	7	4,32	155	95,68	NA	NA	NA	-	-	-	-	0,9668
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	171	9	5,26	162	94,74	NA	NA	NA	1,13	0,45	2,85	0,7895	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	185	10	5,41	175	94,59	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	48	1	2,08	47	97,92	NA	NA	NA	0,51	0,05	5,64	0,5761	0,4683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	47	2	4,26	45	95,74	NA	NA	NA	-	-	-	-	0,4683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	147	11	7,48	136	92,52	NA	NA	NA	1,31	0,55	3,16	0,5391	0,4683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	157	10	6,37	147	93,63	NA	NA	NA	-	-	-	-	0,4683
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	98	4	4,08	94	95,92	NA	NA	NA	0,70	0,20	2,45	0,5701	0,2790
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	104	7	6,73	97	93,27	NA	NA	NA	-	-	-	-	0,2790
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	97	8	8,25	89	91,75	NA	NA	NA	1,77	0,57	5,44	0,3147	0,2790

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	100	5	5,00	95	95,00	NA	NA	NA	-	-	-	-	0,2790
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	98	5	5,10	93	94,90	NA	NA	NA	0,90	0,28	2,89	0,8645	0,6544
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	111	7	6,31	104	93,69	NA	NA	NA	-	-	-	-	0,6544
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	97	7	7,22	90	92,78	NA	NA	NA	1,32	0,41	4,23	0,6433	0,6544
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	93	5	5,38	88	94,62	NA	NA	NA	-	-	-	-	0,6544
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	61	3	4,92	58	95,08	NA	NA	NA	1,13	0,23	5,62	0,8844	0,8753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	62	3	4,84	59	95,16	NA	NA	NA	-	-	-	-	0,8753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	134	9	6,72	125	93,28	NA	NA	NA	1,31	0,49	3,47	0,5862	0,8753
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	142	9	6,34	133	93,66	NA	NA	NA	-	-	-	-	0,8753
Patients with at least one SAE	total	-	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	195	14	7,18	181	92,82	NA	NA	NA	2,91	1,03	8,23	0,0353	NA
Patients with at least one SAE	total	-	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	204	5	2,45	199	97,55	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Gender	Female	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	80	3	3,75	77	96,25	NA	NA	NA	3,85	0,39	37,86	0,2147	0,7122
Patients with at least one SAE	Gender	Female	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	91	1	1,10	90	98,90	NA	NA	NA	-	-	-	-	0,7122
Patients with at least one SAE	Gender	Male	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	115	11	9,57	104	90,43	NA	NA	NA	2,38	0,74	7,66	0,1354	0,7122
Patients with at least one SAE	Gender	Male	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	113	4	3,54	109	96,46	NA	NA	NA	-	-	-	-	0,7122
Patients with at least one SAE	Age Group	<65	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	86	4	4,65	82	95,35	NA	NA	NA	0,88	0,14	5,51	0,8878	0,1582
Patients with at least one SAE	Age Group	<65	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	75	2	2,67	73	97,33	NA	NA	NA	-	-	-	-	0,1582
Patients with at least one SAE	Age Group	>=65	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	109	10	9,17	99	90,83	NA	NA	NA	4,43	1,21	16,27	0,0144	0,1582
Patients with at least one SAE	Age Group	>=65	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	129	3	2,33	126	97,67	NA	NA	NA	-	-	-	-	0,1582
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	173	13	7,51	160	92,49	NA	NA	NA	4,43	1,24	15,85	0,0127	0,1232

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Baseline R-ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	174	3	1,72	171	98,28	NA	NA	NA	-	-	-	-	0,1232
Patients with at least one SAE	Baseline R-ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	12	1	8,33	11	91,67	NA	NA	NA	0,46	0,03	6,09	0,5488	0,1232
Patients with at least one SAE	Baseline R-ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	16	2	12,50	14	87,50	NA	NA	NA	-	-	-	-	0,1232
Patients with at least one SAE	Baseline ISS stage	Stage I or II	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	163	10	6,13	153	93,87	NA	NA	NA	4,02	1,08	14,96	0,0254	0,2204
Patients with at least one SAE	Baseline ISS stage	Stage I or II	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	173	3	1,73	170	98,27	NA	NA	NA	-	-	-	-	0,2204
Patients with at least one SAE	Baseline ISS stage	Stage III	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	32	4	12,50	28	87,50	37,32	37,32	NA	0,91	0,12	6,63	0,9232	0,2204
Patients with at least one SAE	Baseline ISS stage	Stage III	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	31	2	6,45	29	93,55	NA	NA	NA	-	-	-	-	0,2204
Patients with at least one SAE	Region (SAP)	Region 1	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	18	1	5,56	17	94,44	NA	NA	NA	0,79	0,05	12,65	0,8678	0,4747
Patients with at least one SAE	Region (SAP)	Region 1	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	17	1	5,88	16	94,12	NA	NA	NA	-	-	-	-	0,4747
Patients with at least one SAE	Region (SAP)	Region 2	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	61	6	9,84	55	90,16	NA	NA	NA	6,58	0,79	54,70	0,0443	0,4747
Patients with at least one SAE	Region (SAP)	Region 2	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	64	1	1,56	63	98,44	NA	NA	NA	-	-	-	-	0,4747
Patients with at least one SAE	Region (SAP)	Region 3	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	47	1	2,13	46	97,87	-	-	-	-	-	-	-	0,4747
Patients with at least one SAE	Region (SAP)	Region 3	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	53	0	0,00	53	100,00	-	-	-	-	-	-	-	0,4747
Patients with at least one SAE	Region (SAP)	Region 4	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	69	6	8,70	63	91,30	NA	37,32	NA	2,21	0,52	9,51	0,2742	0,4747
Patients with at least one SAE	Region (SAP)	Region 4	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	70	3	4,29	67	95,71	NA	NA	NA	-	-	-	-	0,4747
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	117	5	4,27	112	95,73	NA	NA	NA	1,53	0,36	6,50	0,5611	0,3669
Patients with at least one SAE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	136	3	2,21	133	97,79	NA	NA	NA	-	-	-	-	0,3669
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	78	9	11,54	69	88,46	NA	37,32	NA	4,08	0,86	19,45	0,0568	0,3669
Patients with at least one SAE	Region (by medical care situation)	Rest of the world	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	68	2	2,94	66	97,06	NA	NA	NA	-	-	-	-	0,3669
Patients with at least one SAE	Race	Races other than White	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	34	3	8,82	31	91,18	NA	NA	NA	4,48	0,45	44,80	0,1669	0,6615
Patients with at least one SAE	Race	Races other than White	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	42	1	2,38	41	97,62	NA	NA	NA	-	-	-	-	0,6615
Patients with at least one SAE	Race	White	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	161	11	6,83	150	93,17	NA	NA	NA	2,51	0,79	8,04	0,1075	0,6615

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Race	White	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	162	4	2,47	158	97,53	NA	NA	NA	-	-	-	-	0,6615
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	171	12	7,02	159	92,98	NA	NA	NA	2,61	0,90	7,60	0,0673	NA
Patients with at least one SAE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	185	5	2,70	180	97,30	NA	NA	NA	-	-	-	-	NA
Patients with at least one SAE	Prior PI therapies	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	48	3	6,25	45	93,75	NA	37,32	NA	2,05	0,19	22,62	0,5506	0,7537
Patients with at least one SAE	Prior PI therapies	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	47	1	2,13	46	97,87	NA	NA	NA	-	-	-	-	0,7537
Patients with at least one SAE	Prior PI therapies	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	147	11	7,48	136	92,52	NA	NA	NA	3,14	0,99	9,96	0,0414	0,7537
Patients with at least one SAE	Prior PI therapies	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	157	4	2,55	153	97,45	NA	NA	NA	-	-	-	-	0,7537
Patients with at least one SAE	Prior anti-MM regimen	>1	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	98	6	6,12	92	93,88	NA	NA	NA	3,73	0,74	18,96	0,0898	0,6833
Patients with at least one SAE	Prior anti-MM regimen	>1	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	104	2	1,92	102	98,08	NA	NA	NA	-	-	-	-	0,6833
Patients with at least one SAE	Prior anti-MM regimen	1	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	97	8	8,25	89	91,75	NA	NA	NA	2,40	0,62	9,31	0,1899	0,6833
Patients with at least one SAE	Prior anti-MM regimen	1	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	100	3	3,00	97	97,00	NA	NA	NA	-	-	-	-	0,6833
Patients with at least one SAE	Baseline single cytogenetic alterations	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	98	6	6,12	92	93,88	NA	NA	NA	2,22	0,52	9,52	0,2717	0,7120
Patients with at least one SAE	Baseline single cytogenetic alterations	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	111	3	2,70	108	97,30	NA	NA	NA	-	-	-	-	0,7120
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	97	8	8,25	89	91,75	NA	NA	NA	3,31	0,70	15,63	0,1085	0,7120
Patients with at least one SAE	Baseline single cytogenetic alterations	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	93	2	2,15	91	97,85	NA	NA	NA	-	-	-	-	0,7120
Patients with at least one SAE	Previously Exposed to Bortezomib	N	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	61	5	8,20	56	91,80	NA	NA	NA	4,50	0,50	40,58	0,1421	0,7241

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one SAE	Previously Exposed to Bortezomib	N	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	62	1	1,61	61	98,39	NA	NA	NA	-	-	-	-	0,7241
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	SVd Arm	Respiratory, thoracic and mediastinal disorders	-	134	9	6,72	125	93,28	NA	NA	NA	2,86	0,85	9,66	0,0775	0,7241
Patients with at least one SAE	Previously Exposed to Bortezomib	Y	Vd Arm	Respiratory, thoracic and mediastinal disorders	-	142	4	2,82	138	97,18	NA	NA	NA	-	-	-	-	0,7241
Patients with at least one AE	total	-	SVd Arm	Vascular disorders	Hypotension	195	11	5,64	184	94,36	NA	NA	NA	1,05	0,46	2,40	0,9042	NA
Patients with at least one AE	total	-	Vd Arm	Vascular disorders	Hypotension	204	12	5,88	192	94,12	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Skin and subcutaneous tissue disorders	-	80	21	26,25	59	73,75	NA	23,66	NA	1,92	0,93	3,94	0,0731	0,5515
Patients with at least one AE	Gender	Female	Vd Arm	Skin and subcutaneous tissue disorders	-	91	15	16,48	76	83,52	NA	NA	NA	-	-	-	-	0,5515
Patients with at least one AE	Gender	Male	SVd Arm	Skin and subcutaneous tissue disorders	-	115	25	21,74	90	78,26	32,43	19,91	NA	1,43	0,76	2,69	0,2640	0,5515
Patients with at least one AE	Gender	Male	Vd Arm	Skin and subcutaneous tissue disorders	-	113	17	15,04	96	84,96	NA	NA	NA	-	-	-	-	0,5515
Patients with at least one AE	Age Group	<65	SVd Arm	Skin and subcutaneous tissue disorders	-	86	24	27,91	62	72,09	32,43	14,88	NA	1,29	0,68	2,45	0,4401	0,4173
Patients with at least one AE	Age Group	<65	Vd Arm	Skin and subcutaneous tissue disorders	-	75	17	22,67	58	77,33	NA	21,88	NA	-	-	-	-	0,4173
Patients with at least one AE	Age Group	>=65	SVd Arm	Skin and subcutaneous tissue disorders	-	109	22	20,18	87	79,82	NA	19,91	NA	1,89	0,97	3,69	0,0576	0,4173
Patients with at least one AE	Age Group	>=65	Vd Arm	Skin and subcutaneous tissue disorders	-	129	15	11,63	114	88,37	NA	NA	NA	-	-	-	-	0,4173
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Skin and subcutaneous tissue disorders	-	173	42	24,28	131	75,72	NA	20,07	NA	1,86	1,13	3,06	0,0136	0,7664
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Skin and subcutaneous tissue disorders	-	174	25	14,37	149	85,63	NA	NA	NA	-	-	-	-	0,7664
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Skin and subcutaneous tissue disorders	-	12	3	25,00	9	75,00	32,43	NA	NA	1,35	0,18	10,29	0,7691	0,7664
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Skin and subcutaneous tissue disorders	-	16	4	25,00	12	75,00	NA	5,65	NA	-	-	-	-	0,7664
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Skin and subcutaneous tissue disorders	-	163	41	25,15	122	74,85	NA	19,91	NA	1,76	1,08	2,88	0,0221	0,6296
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Skin and subcutaneous tissue disorders	-	173	27	15,61	146	84,39	NA	NA	NA	-	-	-	-	0,6296
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Skin and subcutaneous tissue disorders	-	32	5	15,62	27	84,38	32,43	32,43	NA	1,22	0,29	5,05	0,7881	0,6296
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Skin and subcutaneous tissue disorders	-	31	5	16,13	26	83,87	NA	NA	NA	-	-	-	-	0,6296
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Skin and subcutaneous tissue disorders	-	18	5	27,78	13	72,22	12,94	11,86	NA	1,25	0,28	5,61	0,7713	0,7799
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Skin and subcutaneous tissue disorders	-	17	5	29,41	12	70,59	NA	4,40	NA	-	-	-	-	0,7799
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Skin and subcutaneous tissue disorders	-	61	20	32,79	41	67,21	19,91	11,33	NA	1,24	0,61	2,50	0,5503	0,7799

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Skin and subcutaneous tissue disorders	-	64	16	25,00	48	75,00	NA	17,68	NA	-	-	-	-	0,7799
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Skin and subcutaneous tissue disorders	-	47	6	12,77	41	87,23	NA	NA	NA	1,81	0,45	7,28	0,3998	0,7799
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Skin and subcutaneous tissue disorders	-	53	3	5,66	50	94,34	NA	NA	NA	-	-	-	-	0,7799
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Skin and subcutaneous tissue disorders	-	69	15	21,74	54	78,26	32,43	32,43	NA	2,18	0,90	5,24	0,0761	0,7799
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Skin and subcutaneous tissue disorders	-	70	8	11,43	62	88,57	NA	NA	NA	-	-	-	-	0,7799
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Skin and subcutaneous tissue disorders	-	117	28	23,93	89	76,07	NA	20,07	NA	1,50	0,85	2,64	0,1584	0,6970
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Skin and subcutaneous tissue disorders	-	136	22	16,18	114	83,82	NA	NA	NA	-	-	-	-	0,6970
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Skin and subcutaneous tissue disorders	-	78	18	23,08	60	76,92	32,43	16,79	NA	1,82	0,82	4,02	0,1337	0,6970
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Skin and subcutaneous tissue disorders	-	68	10	14,71	58	85,29	NA	27,01	NA	-	-	-	-	0,6970
Patients with at least one AE	Race	Races other than White	SVd Arm	Skin and subcutaneous tissue disorders	-	34	7	20,59	27	79,41	32,43	16,79	NA	0,97	0,31	3,00	0,9580	0,3114
Patients with at least one AE	Race	Races other than White	Vd Arm	Skin and subcutaneous tissue disorders	-	42	10	23,81	32	76,19	27,01	21,88	NA	-	-	-	-	0,3114
Patients with at least one AE	Race	White	SVd Arm	Skin and subcutaneous tissue disorders	-	161	39	24,22	122	75,78	NA	20,07	NA	1,85	1,09	3,14	0,0212	0,3114
Patients with at least one AE	Race	White	Vd Arm	Skin and subcutaneous tissue disorders	-	162	22	13,58	140	86,42	NA	NA	NA	-	-	-	-	0,3114
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Skin and subcutaneous tissue disorders	-	6	1	16,67	5	83,33	23,66	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Skin and subcutaneous tissue disorders	-	5	1	20,00	4	80,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Skin and subcutaneous tissue disorders	-	171	41	23,98	130	76,02	32,43	19,91	NA	1,61	1,00	2,59	0,0463	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Skin and subcutaneous tissue disorders	-	185	31	16,76	154	83,24	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Skin and subcutaneous tissue disorders	-	48	11	22,92	37	77,08	NA	16,79	NA	2,28	0,83	6,25	0,0997	0,4739
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Skin and subcutaneous tissue disorders	-	47	6	12,77	41	87,23	NA	27,01	NA	-	-	-	-	0,4739

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Skin and subcutaneous tissue disorders	-	147	35	23,81	112	76,19	32,43	20,07	NA	1,51	0,90	2,52	0,1132	0,4739
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Skin and subcutaneous tissue disorders	-	157	26	16,56	131	83,44	NA	NA	NA	-	-	-	-	0,4739
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Skin and subcutaneous tissue disorders	-	98	21	21,43	77	78,57	NA	15,84	NA	1,17	0,63	2,17	0,6156	0,1164
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Skin and subcutaneous tissue disorders	-	104	20	19,23	84	80,77	NA	27,01	NA	-	-	-	-	0,1164
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Skin and subcutaneous tissue disorders	-	97	25	25,77	72	74,23	32,43	20,07	NA	2,47	1,23	4,95	0,0087	0,1164
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Skin and subcutaneous tissue disorders	-	100	12	12,00	88	88,00	NA	NA	NA	-	-	-	-	0,1164
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Skin and subcutaneous tissue disorders	-	98	23	23,47	75	76,53	32,43	23,66	NA	1,35	0,74	2,48	0,3289	0,3790
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Skin and subcutaneous tissue disorders	-	111	21	18,92	90	81,08	NA	27,01	NA	-	-	-	-	0,3790
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Skin and subcutaneous tissue disorders	-	97	23	23,71	74	76,29	NA	19,91	NA	2,08	0,98	4,40	0,0499	0,3790
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Skin and subcutaneous tissue disorders	-	93	11	11,83	82	88,17	NA	NA	NA	-	-	-	-	0,3790
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Skin and subcutaneous tissue disorders	-	61	14	22,95	47	77,05	NA	16,79	NA	1,97	0,81	4,81	0,1304	0,6789
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Skin and subcutaneous tissue disorders	-	62	9	14,52	53	85,48	NA	27,01	NA	-	-	-	-	0,6789
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Skin and subcutaneous tissue disorders	-	134	32	23,88	102	76,12	32,43	20,07	NA	1,58	0,92	2,72	0,0966	0,6789
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Skin and subcutaneous tissue disorders	-	142	23	16,20	119	83,80	NA	NA	NA	-	-	-	-	0,6789
Patients with at least one AE	total	-	SVd Arm	Vascular disorders	-	195	36	18,46	159	81,54	NA	NA	NA	0,87	0,56	1,38	0,5621	NA
Patients with at least one AE	total	-	Vd Arm	Vascular disorders	-	204	42	20,59	162	79,41	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Gender	Female	SVd Arm	Vascular disorders	-	80	20	25,00	60	75,00	NA	17,94	NA	1,18	0,62	2,25	0,6225	0,2222
Patients with at least one AE	Gender	Female	Vd Arm	Vascular disorders	-	91	21	23,08	70	76,92	NA	21,72	NA	-	-	-	-	0,2222
Patients with at least one AE	Gender	Male	SVd Arm	Vascular disorders	-	115	16	13,91	99	86,09	NA	NA	NA	0,66	0,34	1,29	0,2181	0,2222
Patients with at least one AE	Gender	Male	Vd Arm	Vascular disorders	-	113	21	18,58	92	81,42	NA	NA	NA	-	-	-	-	0,2222
Patients with at least one AE	Age Group	<65	SVd Arm	Vascular disorders	-	86	19	22,09	67	77,91	NA	37,42	NA	1,37	0,62	3,00	0,4304	0,1659
Patients with at least one AE	Age Group	<65	Vd Arm	Vascular disorders	-	75	10	13,33	65	86,67	NA	21,72	NA	-	-	-	-	0,1659
Patients with at least one AE	Age Group	>=65	SVd Arm	Vascular disorders	-	109	17	15,60	92	84,40	NA	NA	NA	0,68	0,38	1,24	0,2056	0,1659
Patients with at least one AE	Age Group	>=65	Vd Arm	Vascular disorders	-	129	32	24,81	97	75,19	NA	NA	NA	-	-	-	-	0,1659
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	SVd Arm	Vascular disorders	-	173	35	20,23	138	79,77	NA	NA	NA	0,94	0,59	1,51	0,8002	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Baseline R-ISS stage	Stage I or II	Vd Arm	Vascular disorders	-	174	36	20,69	138	79,31	NA	21,72	NA	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	SVd Arm	Vascular disorders	-	12	0	0,00	12	100,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline R-ISS stage	Stage III	Vd Arm	Vascular disorders	-	16	4	25,00	12	75,00	-	-	-	-	-	-	-	NA
Patients with at least one AE	Baseline ISS stage	Stage I or II	SVd Arm	Vascular disorders	-	163	31	19,02	132	80,98	NA	NA	NA	0,89	0,55	1,44	0,6278	0,4737
Patients with at least one AE	Baseline ISS stage	Stage I or II	Vd Arm	Vascular disorders	-	173	37	21,39	136	78,61	NA	NA	NA	-	-	-	-	0,4737
Patients with at least one AE	Baseline ISS stage	Stage III	SVd Arm	Vascular disorders	-	32	5	15,62	27	84,38	37,42	37,42	NA	1,59	0,35	7,23	0,5470	0,4737
Patients with at least one AE	Baseline ISS stage	Stage III	Vd Arm	Vascular disorders	-	31	5	16,13	26	83,87	NA	18,50	NA	-	-	-	-	0,4737
Patients with at least one AE	Region (SAP)	Region 1	SVd Arm	Vascular disorders	-	18	6	33,33	12	66,67	11,86	6,01	NA	1,55	0,25	9,55	0,6342	0,8334
Patients with at least one AE	Region (SAP)	Region 1	Vd Arm	Vascular disorders	-	17	4	23,53	13	76,47	NA	10,78	NA	-	-	-	-	0,8334
Patients with at least one AE	Region (SAP)	Region 2	SVd Arm	Vascular disorders	-	61	15	24,59	46	75,41	NA	17,94	NA	1,01	0,49	2,10	0,9762	0,8334
Patients with at least one AE	Region (SAP)	Region 2	Vd Arm	Vascular disorders	-	64	17	26,56	47	73,44	18,53	15,38	NA	-	-	-	-	0,8334
Patients with at least one AE	Region (SAP)	Region 3	SVd Arm	Vascular disorders	-	47	5	10,64	42	89,36	NA	NA	NA	0,62	0,20	1,88	0,3939	0,8334
Patients with at least one AE	Region (SAP)	Region 3	Vd Arm	Vascular disorders	-	53	11	20,75	42	79,25	NA	NA	NA	-	-	-	-	0,8334
Patients with at least one AE	Region (SAP)	Region 4	SVd Arm	Vascular disorders	-	69	10	14,49	59	85,51	NA	37,42	NA	0,92	0,37	2,28	0,8567	0,8334
Patients with at least one AE	Region (SAP)	Region 4	Vd Arm	Vascular disorders	-	70	10	14,29	60	85,71	NA	NA	NA	-	-	-	-	0,8334
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Vascular disorders	-	117	23	19,66	94	80,34	NA	NA	NA	0,77	0,45	1,33	0,3447	0,3493
Patients with at least one AE	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Vascular disorders	-	136	33	24,26	103	75,74	NA	18,53	NA	-	-	-	-	0,3493
Patients with at least one AE	Region (by medical care situation)	Rest of the world	SVd Arm	Vascular disorders	-	78	13	16,67	65	83,33	NA	37,42	NA	1,26	0,53	3,00	0,6055	0,3493
Patients with at least one AE	Region (by medical care situation)	Rest of the world	Vd Arm	Vascular disorders	-	68	9	13,24	59	86,76	NA	NA	NA	-	-	-	-	0,3493
Patients with at least one AE	Race	Races other than White	SVd Arm	Vascular disorders	-	34	7	20,59	27	79,41	NA	8,08	NA	1,35	0,45	4,06	0,5889	0,3957
Patients with at least one AE	Race	Races other than White	Vd Arm	Vascular disorders	-	42	8	19,05	34	80,95	NA	18,53	NA	-	-	-	-	0,3957
Patients with at least one AE	Race	White	SVd Arm	Vascular disorders	-	161	29	18,01	132	81,99	NA	NA	NA	0,80	0,48	1,33	0,3888	0,3957
Patients with at least one AE	Race	White	Vd Arm	Vascular disorders	-	162	34	20,99	128	79,01	NA	NA	NA	-	-	-	-	0,3957
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	SVd Arm	Vascular disorders	-	6	2	33,33	4	66,67	-	-	-	-	-	-	-	NA
Patients with at least one AE	Ethnicity	HISPANIC OR LATINO	Vd Arm	Vascular disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Vascular disorders	-	171	31	18,13	140	81,87	NA	NA	NA	0,85	0,53	1,38	0,5204	NA
Patients with at least one AE	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Vascular disorders	-	185	39	21,08	146	78,92	NA	NA	NA	-	-	-	-	NA
Patients with at least one AE	Prior PI therapies	N	SVd Arm	Vascular disorders	-	48	7	14,58	41	85,42	NA	37,42	NA	0,69	0,24	1,96	0,4799	0,6143
Patients with at least one AE	Prior PI therapies	N	Vd Arm	Vascular disorders	-	47	9	19,15	38	80,85	NA	NA	NA	-	-	-	-	0,6143
Patients with at least one AE	Prior PI therapies	Y	SVd Arm	Vascular disorders	-	147	29	19,73	118	80,27	NA	NA	NA	0,93	0,56	1,53	0,7631	0,6143
Patients with at least one AE	Prior PI therapies	Y	Vd Arm	Vascular disorders	-	157	33	21,02	124	78,98	NA	21,72	NA	-	-	-	-	0,6143
Patients with at least one AE	Prior anti-MM regimen	>1	SVd Arm	Vascular disorders	-	98	14	14,29	84	85,71	NA	NA	NA	0,72	0,37	1,43	0,3490	0,4586
Patients with at least one AE	Prior anti-MM regimen	>1	Vd Arm	Vascular disorders	-	104	21	20,19	83	79,81	NA	18,53	NA	-	-	-	-	0,4586
Patients with at least one AE	Prior anti-MM regimen	1	SVd Arm	Vascular disorders	-	97	22	22,68	75	77,32	NA	37,42	NA	1,02	0,56	1,88	0,9451	0,4586
Patients with at least one AE	Prior anti-MM regimen	1	Vd Arm	Vascular disorders	-	100	21	21,00	79	79,00	NA	NA	NA	-	-	-	-	0,4586
Patients with at least one AE	Baseline single cytogenetic alterations	N	SVd Arm	Vascular disorders	-	98	16	16,33	82	83,67	NA	NA	NA	0,72	0,38	1,38	0,3203	0,4080
Patients with at least one AE	Baseline single cytogenetic alterations	N	Vd Arm	Vascular disorders	-	111	24	21,62	87	78,38	NA	NA	NA	-	-	-	-	0,4080
Patients with at least one AE	Baseline single cytogenetic alterations	Y	SVd Arm	Vascular disorders	-	97	20	20,62	77	79,38	NA	NA	NA	1,06	0,56	2,02	0,8602	0,4080
Patients with at least one AE	Baseline single cytogenetic alterations	Y	Vd Arm	Vascular disorders	-	93	18	19,35	75	80,65	NA	NA	NA	-	-	-	-	0,4080
Patients with at least one AE	Previously Exposed to Bortezomib	N	SVd Arm	Vascular disorders	-	61	9	14,75	52	85,25	NA	37,42	NA	0,68	0,28	1,65	0,3885	0,4224
Patients with at least one AE	Previously Exposed to Bortezomib	N	Vd Arm	Vascular disorders	-	62	14	22,58	48	77,42	NA	NA	NA	-	-	-	-	0,4224
Patients with at least one AE	Previously Exposed to Bortezomib	Y	SVd Arm	Vascular disorders	-	134	27	20,15	107	79,85	NA	NA	NA	1,04	0,61	1,77	0,8963	0,4224
Patients with at least one AE	Previously Exposed to Bortezomib	Y	Vd Arm	Vascular disorders	-	142	28	19,72	114	80,28	NA	NA	NA	-	-	-	-	0,4224

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	SVd Arm	Vascular disorders	-	195	14	7,18	181	92,82	NA	NA	NA	1,11	0,53	2,33	0,7891	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	total	-	Vd Arm	Vascular disorders	-	204	14	6,86	190	93,14	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	SVd Arm	Vascular disorders	-	80	8	10,00	72	90,00	NA	NA	NA	1,61	0,56	4,69	0,3748	0,4370
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Female	Vd Arm	Vascular disorders	-	91	7	7,69	84	92,31	NA	NA	NA	-	-	-	-	0,4370
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	SVd Arm	Vascular disorders	-	115	6	5,22	109	94,78	NA	NA	NA	0,88	0,29	2,63	0,8191	0,4370
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Gender	Male	Vd Arm	Vascular disorders	-	113	7	6,19	106	93,81	NA	NA	NA	-	-	-	-	0,4370
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	SVd Arm	Vascular disorders	-	86	9	10,47	77	89,53	NA	NA	NA	2,43	0,65	9,16	0,1760	0,1144
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	<65	Vd Arm	Vascular disorders	-	75	3	4,00	72	96,00	NA	NA	NA	-	-	-	-	0,1144
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	SVd Arm	Vascular disorders	-	109	5	4,59	104	95,41	NA	NA	NA	0,62	0,21	1,79	0,3716	0,1144
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Age Group	>=65	Vd Arm	Vascular disorders	-	129	11	8,53	118	91,47	NA	NA	NA	-	-	-	-	0,1144
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	SVd Arm	Vascular disorders	-	173	13	7,51	160	92,49	NA	NA	NA	0,99	0,46	2,13	0,9890	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage I or II	Vd Arm	Vascular disorders	-	174	14	8,05	160	91,95	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	SVd Arm	Vascular disorders	-	12	0	0,00	12	100,00	NA	NA	NA	NA	NA	NA	1,0000	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline R-ISS stage	Stage III	Vd Arm	Vascular disorders	-	16	0	0,00	16	100,00	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	SVd Arm	Vascular disorders	-	163	12	7,36	151	92,64	NA	NA	NA	1,10	0,49	2,47	0,8109	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage I or II	Vd Arm	Vascular disorders	-	173	13	7,51	160	92,49	NA	NA	NA	-	-	-	-	NA

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	SVd Arm	Vascular disorders	-	32	2	6,25	30	93,75	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline ISS stage	Stage III	Vd Arm	Vascular disorders	-	31	1	3,23	30	96,77	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	SVd Arm	Vascular disorders	-	18	3	16,67	15	83,33	-	-	-	-	-	-	-	0,4512
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 1	Vd Arm	Vascular disorders	-	17	1	5,88	16	94,12	-	-	-	-	-	-	-	0,4512
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	SVd Arm	Vascular disorders	-	61	6	9,84	55	90,16	NA	NA	NA	1,60	0,45	5,67	0,4631	0,4512
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 2	Vd Arm	Vascular disorders	-	64	4	6,25	60	93,75	NA	NA	NA	-	-	-	-	0,4512
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	SVd Arm	Vascular disorders	-	47	1	2,13	46	97,87	NA	NA	NA	0,31	0,03	3,17	0,3035	0,4512
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 3	Vd Arm	Vascular disorders	-	53	4	7,55	49	92,45	NA	NA	NA	-	-	-	-	0,4512
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	SVd Arm	Vascular disorders	-	69	4	5,80	65	94,20	NA	NA	NA	0,80	0,21	3,00	0,7423	0,4512
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (SAP)	Region 4	Vd Arm	Vascular disorders	-	70	5	7,14	65	92,86	NA	NA	NA	-	-	-	-	0,4512
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	SVd Arm	Vascular disorders	-	117	8	6,84	109	93,16	NA	NA	NA	1,04	0,39	2,75	0,9355	0,7285
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	EU incl, UK + North America	Vd Arm	Vascular disorders	-	136	10	7,35	126	92,65	NA	NA	NA	-	-	-	-	0,7285
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	SVd Arm	Vascular disorders	-	78	6	7,69	72	92,31	NA	NA	NA	1,38	0,39	4,92	0,6164	0,7285
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Region (by medical care situation)	Rest of the world	Vd Arm	Vascular disorders	-	68	4	5,88	64	94,12	NA	NA	NA	-	-	-	-	0,7285
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	SVd Arm	Vascular disorders	-	34	3	8,82	31	91,18	NA	NA	NA	1,44	0,28	7,33	0,6598	0,7030
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	Races other than White	Vd Arm	Vascular disorders	-	42	3	7,14	39	92,86	NA	NA	NA	-	-	-	-	0,7030

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Median Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	SVd Arm	Vascular disorders	-	161	11	6,83	150	93,17	NA	NA	NA	1,01	0,43	2,35	0,9874	0,7030
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Race	White	Vd Arm	Vascular disorders	-	162	11	6,79	151	93,21	NA	NA	NA	-	-	-	-	0,7030
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	SVd Arm	Vascular disorders	-	6	1	16,67	5	83,33	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	HISPANIC OR LATINO	Vd Arm	Vascular disorders	-	5	0	0,00	5	100,00	-	-	-	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	SVd Arm	Vascular disorders	-	171	13	7,60	158	92,40	NA	NA	NA	1,17	0,54	2,53	0,6980	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Ethnicity	NOT HISPANIC OR LATINO	Vd Arm	Vascular disorders	-	185	13	7,03	172	92,97	NA	NA	NA	-	-	-	-	NA
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	SVd Arm	Vascular disorders	-	48	1	2,08	47	97,92	NA	NA	NA	0,25	0,03	2,27	0,1848	0,1411
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	N	Vd Arm	Vascular disorders	-	47	4	8,51	43	91,49	NA	NA	NA	-	-	-	-	0,1411
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	SVd Arm	Vascular disorders	-	147	13	8,84	134	91,16	NA	NA	NA	1,47	0,64	3,38	0,3581	0,1411
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior PI therapies	Y	Vd Arm	Vascular disorders	-	157	10	6,37	147	93,63	NA	NA	NA	-	-	-	-	0,1411
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	SVd Arm	Vascular disorders	-	98	6	6,12	92	93,88	NA	NA	NA	0,85	0,29	2,46	0,7577	0,4861
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	>1	Vd Arm	Vascular disorders	-	104	8	7,69	96	92,31	NA	NA	NA	-	-	-	-	0,4861
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	SVd Arm	Vascular disorders	-	97	8	8,25	89	91,75	NA	NA	NA	1,44	0,50	4,17	0,4952	0,4861
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Prior anti-MM regimen	1	Vd Arm	Vascular disorders	-	100	6	6,00	94	94,00	NA	NA	NA	-	-	-	-	0,4861
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	SVd Arm	Vascular disorders	-	98	7	7,14	91	92,86	NA	NA	NA	1,43	0,47	4,33	0,5248	0,5220

Endpunkt	Subgruppenmerkmal	Sub-gruppe	Studienarm	SOC	PT	N	Patienten mit Ereignis, n	Patienten mit Ereignis, %	Zensierte Patienten, n	Zensierte Patienten, %	Mediane Zeit bis Ereignis in Monaten	Unteres 95 %-KI der medianen Zeit bis Ereignis	Oberes 95 %-KI der medianen Zeit bis Ereignis	HR	Unteres 95 %-KI des HR	Oberes 95 %-KI des HR	p-Wert (Log-Rang)	Interaktions-p-Wert
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	N	Vd Arm	Vascular disorders	-	111	6	5,41	105	94,59	NA	NA	NA	-	-	-	-	0,5220
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	SVd Arm	Vascular disorders	-	97	7	7,22	90	92,78	NA	NA	NA	0,87	0,31	2,45	0,7946	0,5220
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Baseline single cytogenetic alterations	Y	Vd Arm	Vascular disorders	-	93	8	8,60	85	91,40	NA	NA	NA	-	-	-	-	0,5220
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	SVd Arm	Vascular disorders	-	61	2	3,28	59	96,72	NA	NA	NA	0,44	0,09	2,28	0,3157	0,1866
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	N	Vd Arm	Vascular disorders	-	62	5	8,06	57	91,94	NA	NA	NA	-	-	-	-	0,1866
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	SVd Arm	Vascular disorders	-	134	12	8,96	122	91,04	NA	NA	NA	1,55	0,64	3,74	0,3261	0,1866
Patients with at least one severe AE (CTCAE v4,03 grade 3 or larger)	Previously Exposed to Bortezomib	Y	Vd Arm	Vascular disorders	-	142	9	6,34	133	93,66	NA	NA	NA	-	-	-	-	0,1866